The Efficacy of a Forearm Rotation Orthosis for Persons with a Hemiparetic Arm

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Abstract

Objectives. To examine the efficacy of a dynamic forearm rotation orthosis used as the sole intervention and in combination with the Occupational Therapy Task-Oriented (OTTO) approach as well as to evaluate the efficacy of the OTTO approach on the functional performance of persons post-stroke with a hemiparetic arm.

Method. A matched, randomized, two- group, single-blinded, repeated measures designed was used. Volunteer sample of persons with chronic stroke (N=14) were first matched on motor function and then randomly assigned to Group A or B. Group A (N=8) experienced six weeks of orthotic intervention followed by six weeks of orthosis plus OTTO intervention (3 hour/week for 6 weeks). Group B (N=6) experience no treatment for six weeks followed by another six weeks of OTTO intervention. The primary outcome measures were functional performance, including self-perceived performance and satisfaction (Canadian Occupational Performance Measure (COPM)), motor function (Wolf Motor Function Test (WMFT)), and self-reported use of the affected limb (Motor Activity Log (MAL)). The secondary outcome measures were impairments, including active range of motion and strength of the upper extremity, grip, and pinch. Participants were evaluated before and after each intervention phase.

Results. No significant differences were found between participants who received orthotic intervention and those who had no treatment. By the end of study, participants who receive the OTTO intervention as the sole intervention and in combination with orthosis showed clinically important improvements in self-perceived performance and satisfaction on the COPM and statistical significant improvement in self-report amount

and quality of use of the affected limb on the MAL. No significant differences in functional performance and impairment measures were found between participants who received the OTTO intervention as the sole intervention and in combination with the orthosis.

Conclusions. The 6 weeks of functional training protocol provided clinically important benefits to persons post-stroke in self-perceived functional performance (COPM), but not in motor function (WMFT) and impairment measures (active ROM and strength of UE, grip, and pinch). However, due to technical failure for monitoring adherence to orthotic use, the efficacy of the forearm rotation orthosis for persons post-stroke remains unclear.

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After a stroke, persons often have difficulty incorporating their affected limb into functional tasks/activities due to muscle weakness and/or spasticity (Gillen & Nilsen, 2016). Ineffective functional use of the affected limb may lead to learned nonuse (Taub, Uswatte, & Pidikiti, 1999), reliance on inefficient compensatory movement patterns (Mackey, Walt, & Stoot, 2006), and development of muscle or joint contracture (Gillen, 2016). Traditional rehabilitation interventions for persons post-stroke emphasize spasticity reduction and exercise of isolated active joint movement, including flexion and extension movement of wrist, hand, and elbow (Gillen & Nilsen, 2016). The role of forearm movement is often ignored despite evidence that active range and muscle strength of forearm supination are associated with functional recovery post-stroke (Braendvik, Elvrum, Vereijken, & Roeleveld, 2010; O'Dwyer, Ada, & Neilson, 1996).

In addition, Nilsen, Gillen, Geller, Hreha, Osei, and Saleem (2015) suggested that intervention for stroke population is more effective when the content is composed of individualized, goal-directed tasks that encourage repetitive practice of tasks-related/specific movements. Such treatment is at the core of both the Occupational Therapy Task-Oriented (OTTO) approach (Almhdawi, Mathiowetz, White, & delMas, 2016; Flinn, 1995) and the Constraint-Induced Movement Therapy (CIMT) (Dunning et al., 2008; Page, Levine, & Leonard, 2005; Page, Levine, Leonard, Szaflarski, & Kissela, 2008; Taub, Uswatte, & Elbert, 2002; Taub et al., 2006;Wolf et al., 2008). CIMT aims to improve motor function by forced use of the affected limb (Taub, Uswatte, & Pidikiti,

1999), whereas the OTTO aims to maximize the person's functional performance necessary to his/her life roles (Mathiowetz, 2016) by practicing tasks chosen by the clients. Both CIMT and OTTO stress actual use of the affected limb, but neither explicitly addresses the role of forearm rotation movements in the training protocol.

In an effort to reduce post-stroke spasticity and prevent deformity in the hand and wrist, several orthotic designs focus on keeping muscles and soft tissues in functional length by immobilizing the wrist and/or hand (Gillen, 2016). The effects of these orthoses on spasticity are questionable (Lannin & Herbert, 2003). In addition, many of these "antispasticity" orthoses are thought to interfere with functional performance, facilitate compensatory movements that interfere with therapeutic neuroplasticity (Pitts & O'Brien, 2008), and further develop the learned nonuse of the affected limb (Gillen, 2016). Given the unproven effects of immobilization orthoses and their known interference during functional hand use, this paper suggested a dynamic/mobilization orthosis as an adjunct to post-stroke functional training. Specifically, it proposed a dynamic orthosis that assists forearm rotation to enhance functional performance. The purpose of this research project was to investigate the efficacy of a dynamic forearm rotation orthosis combined with the OTTO approach on the functional performance of persons post-stroke with a hemiparetic arm.

Review of Literature

Kinematics of the Upper Extremity during Functional Tasks

Performance of functional tasks requires coordination of multiple joints of the upper extremity (UE). Elbow flexion and forearm rotation were identified as important factors

for upper extremity functional tasks in addition to hand movements and shoulder movements (i.e., flexion, abduction, and internal rotation) (Butler, Ladd, Louie, & LaMont, 2010; Safaee-Rad, Shedyk, Quanbury, & Cooper, 1990). Persons with difficulties initiating the primary muscles required for a functional task tend to use excessive compensatory movements at adjacent joints (Mackey, Walt, & Stott, 2006; Pereira, Thambyah, & Lee, 2012). These movements may account for ineffective and inefficient performance in functional tasks (Butler, Ladd, Louie, & LaMont, 2010; Mackey, Walt, & Stott, 2006; Pereira, Thambyah, & Lee, 2012).

Two studies used 3-dimensional kinematic analyses to determine functional range of UE on selected daily activities. van Andel et al. (2008) investigated four movements, which simulated daily activities in 10 healthy adult participants: 1) hand to the contralateral shoulder, 2) hand to mouth, 3) combing hair, and 4) hand to back pocket. Participants showed great variation in wrist flexion and forearm movement during the combing task and large increased shoulder internal rotation and decreased forearm pronation in the hand to back pocket task. The researchers concluded that functional range of motion (ROM) required for these activities was: 1) at least 85 degrees of elbow flexion, 2) neutral wrist position, 3) at least 70 degrees of shoulder flexion, and 4) forearm pronation/supination ranging 40-160 degrees from anatomical position. Safaee-Rad, Shedyk, Quanbury, and Cooper (1990) analyzed the UE kinematics on three actual feeding tasks with 10 healthy participants: 1) drinking with a handled cup; 2) eating with a spoon, and 3) eating with a fork. They found that the drinking task had the greatest arc of shoulder abduction (25 degrees) and elbow motion (60 degrees) and forearm motion

limited to supination. The two eating tasks required both pronation and supination and had the greatest arc of forearm motion when eating with a fork (40 degrees of pronation and 60 degrees of supination). Both studies showed comparable forearm movement in feeding tasks that require at least 35 degrees of pronation and 60 degrees of supination.

Two studies compared the UE kinematics of healthy participants to persons with cerebral palsy. Butler et al. (2010) examined the kinematics of a drinking task that required the participants to reach, grasp cylinder cup, transport to mouth, transport back to table, release cylinder, and return to the starting position on 25 healthy and two children with spastic cerebral palsy (CP). In the healthy group, the elbow motion had the greatest total joint excursion (80 ± 11degrees), followed by pronation-supination (49 ± 12 degrees), shoulder elevation (41 ± 10 degrees), wrist flexion-extension (37 ± 11 degrees), shoulder rotation (19 ± 6 degrees), wrist deviation (12 ± 3 degrees), trunk rotation (7 ± 3 degrees), and trunk flexion-extension (3 ± 2 degrees). Compared to the healthy group, the two children with CP showed increased shoulder internal rotation while reaching and reduced elbow extension at the end of reach. However, the two differed greatly in forearm rotation as one subject with less forearm rotation showed more trunk flexion than the other. Mackey et al. (2006) examined kinematics and timing of 10 typically developing children and 10 children with CP. Both sets of children had similar kinematic patterns but as in Butler et al.'s work, those with CP had increased shoulder internal rotation during reach and reduced elbow extension at the end of reach. They indicated that in the hand to mouth task, children with hemiplegia showed significantly less supination and shoulder flexion and increased compensatory trunk flexion compared with

the healthy controls. Moreover, children with hemiplegia had significantly more time taken and slower movement velocities to complete tasks than healthy controls.

Difficulty in initiating key muscles for the tasks may account for employment of compensatory movements in persons with CNS dysfunction (Butler, Ladd, Louie, & LaMont, 2010; Mackey, Walt, & Stott, 2006; Pereira, Thambyah, & Lee, 2012). Although Butler et al. (2010) ascribed shoulder variability between the participants with CP to different original trunk positions during the task, Pereira et al. (2012) suggested that insufficient active forearm rotation movements may contribute strongly to ineffective and inefficient functional performance. Biomechanically, while carrying an object, the forearm shifts the weight load from the distal part of the UE to the proximal part, to allow effective and efficient implementation of the task (Lee, LaStayo, & von Kersburg, 2003). Positions of forearm are significantly associated with grip strength, with the strongest grip in seen when the forearm is supinated in 90 degrees followed by those seen when it is in neutral and lowest grip strengths associated with pronation to 90 degrees (Richards, Olson, & Palmiter-Thomas, 1996).

In their study of six healthy adults performing five functional tasks that require forearm pronation and supination, Pereira et al (2012) found that when active forearm movements are limited, a person often employs compensatory movements. Participants performed three open-chain activities (i.e., feeding with a spoon, taking a card from a shirt pocket and insert it into a card slot, and answering the phone) and two close-chain activities (i.e., turning a doorknob and using a screwdriver) with their dominant forearm immobilized in either neutral or full supination. Participants used more shoulder

abduction-adduction and internal-external rotation to complete all tasks when active forearm rotation was limited, as opposed to when the forearm was free to move. Notably, more shoulder compensatory movements are observed when the forearm was fixed in a more supinated position.

Results from kinematic studies not only indicate the necessity of coordination among all UE joints, but also highlight forearm rotation movements during functional tasks, particularly in feeding activities. When active forearm rotation is limited, study participants tend to have excessive trunk flexion and/or shoulder rotation and require more time for task completion. This suggests the importance of active forearm rotation movements in functional training for persons post-stroke.

Factors Contributing to Poor Motor Performance

Symptoms post-stroke are typically classified as *positive* or *negative* (Gillen & Nilsen, 2016). Positive symptoms are disruptive to function when present, including spasticity, increased deep tendon reflexes, and hyperactive flexion reflexes (Gillen & Nilsen, 2016). Negative symptoms are those symptoms that affect function by their absence, e.g., loss of dexterity, loss of strength, and restricted ability to move (Gillen & Nilsen, 2016). There was a long theorized causal relation between positive and negative symptoms (Gillen & Nilsen, 2016). However, research evidence has not supported this theory of direct causal relation between positive and negative symptoms. O'Dwyer, Ada, and Neilson (1996) found no association between spasticity and muscle weakness or loss of dexterity in 24 participants post-stroke within one year. Sommerfeld, Eek, Svensson, and Holmqvist (2004) reported that only 19% of their stroke participants with

hemiparesis developed spasticity. Of 95 patients with a first stroke, Sommerfeld et al. (2004) reported that 77 (81%) participants had hemiparesis at initial evaluation with 20 (26%) of those demonstrating spasticity. At the three-month evaluation of the same sample, 64 (67%) had hemiparesis, but only 18 (19%) were identified as spastic type. Furthermore, even though spasticity and weakness are both contributors for contracture in persons with first stroke for a year, Ada, O'Dwyer, and O'Neill (2006) identified weakness as the sole factor significantly associated with limitations in physical activities.

Ineffective voluntary movement control leads to inefficient performance (Beer, Dewald, and Rymer, 2000). In kinematic analyses of multiple UE joints while the forearm was immobilized in full pronation, they found that in relation to shoulder, the elbow of the paretic arm tended to be misdirected at the beginning of reach and then to correct their movement halfway toward the target. Participants were able to re-adjust the affected shoulder and elbow concerning changes in target location but have difficulty pairing the behavioral output with task requirements. As a result, study participants showed excessive elbow movements in relation to shoulder movement in the reach-to-point task compared to healthy controls. The researchers proposed that the observed inefficient performance might result from the ineffective movement following brain injury or secondary to disuse of the affected limb.

Weakness in agonist muscles plays the major role in voluntary movement control in persons with a spastic arm (Fellows, Kaus, & Thilmann, 1994). Fellows and coworkers (1994) used single joint (elbow) electromyography (EMG) to examine the relationship between agonist and antagonist on motor disturbance after stroke. The researchers found

that, compared to healthy controls, the antagonist/extensor activity of elbow in stroke participants was at a comparable level when moving against resistance. They suggested that insufficient function in agonist/flexor muscle is the major factor for disturbance of voluntary movement in persons with hemiparesis.

Braendvik, Elvrum, Vereijken, and Roeleveld (2010) indicated that limited active forearm rotation movements and insufficient muscle strength of the involved UE might account for inefficient and ineffective functional performance in persons with a spastic arm. They examined the relationship between neuromuscular body function (active ROM, muscle tone, maximum muscle strength), force control, and actual functional use of the affected elbow, forearm, and hand (measured by the Assisting Hand Assessment) with a sample of 23 spastic CP participants (21 were hemiplegic and two were diplegic). They reported that functional hand use was significantly associated with the combined of total strength of the UE (bilateral, r_s=.81, p<.05; unilateral, r_s=.73, p<.05) and with active ROM of forearm supination (bilateral, r=.80, p<.05; unilateral, r_s=.81, p<.05). Notably, muscle tone (i.e., degree of spasticity), was not found to be significantly associated with functional hand use.

The importance of UE strengthening for the post-stroke population was confirmed via a meta-analysis that showed that strengthening programs, ranging from 2 to 12 weeks, improved muscle strength and activity implementation for persons with acute and/or chronic stroke without increasing spasticity (Ada, Dorsch, & Canning, 2006). Moreover, training of active forearm movements might be beneficial for persons post-stroke (Lambercy et al., 2011). Lambercy et al. (2011) conducted a six-week intervention of

three-hours per week (total 18 hours) of robot-assisted rehabilitation practice of grasping and forearm pronation/supination exercises. After completion of the grasp and forearm movement training, study participants showed significant improvement in wrist-hand items of the *Fugl-Meyer* motor assessment (Friedman $p < .001$) as well as in shoulder-elbow scores in the *Motricity Index* (Friedman $p < .002$). Six weeks post discontinuation of intervention, the distal arm showed significantly greater improvement than did the proximal arm; however, it is not clear whether these changes in motor function resulted in improved functional performances because that was not measured.

The existing research suggests that limited muscle strength and active ROM of UE are the primary factors associated with ineffective and inefficient functional hand use for stroke population rather than spasticity. In particular, weakness of agonist and ROM of forearm rotation are keys in the UE kinematics. Thus, the long ignored forearm rotation movement especially as it is practiced in functional tasks may hold a key place for intervention for this population toward functional recovery of motion. This suggests that there is a need for stroke interventions, which focus on increasing active forearm ROM and overall muscle strength of the involved UE.

Traditional Perspectives on Motor Control and Motor Learning

In many of the traditional post-stroke treatments (e.g., Bobath), spasticity was regarded as a key contributor to poor motor performance (Bobath, 1948). The presence of spasticity was thought to create difficulty in activating rapid alternating movement, changeable muscle tone when the person's position is changed, and stereotypic

movement patterns in the involved limb(s). Management of spasticity may involve treatment of neural and non-neural factors (Gillen & Nilsen, 2016).

Traditional perspectives of motor control and motor learning assumed that human behavior is a combination of reflexes and that the brain controls the musculoskeletal system in a hierarchical manner (Bobath, 1948; Voss, Ionta, & Myers, 1985). Thus, early treatment theorists (e.g., Bobaths, Knott and Voss) theorized that human movements/behaviors follow a set developmental sequence as the brain matures. Motor and sensory deficits were attributed to the CNS injury and it was believed that interventions should begin at the person's current level of development and progress toward the next level when the person gained control of the current level (Voss, Ionta, & Myers, 1985).

Approaches consistent with traditional perspectives for motor control and motor learning are proprioceptive neuromuscular facilitation (PNF) (Voss, Ionta, & Myers, 1985) and Neurodevelopment Treatment (NDT) approach (Bobath, 1948). These approaches focus on remediating the motor and sensory deficits according to the developmental sequence. PNF uses maximal resistance to balance power of antagonistic patterns of motions through full available ROM to facilitate coordinated performance (Voss, Ionta, & Myers, 1985). NDT emphasizes management of abnormal muscle tone and movement control through appropriate sensory messages to normalize the abnormal muscle tone, retrain normal movement responses, and thus increase functional use of the hemiparetic side (Bobath, 1948).

The motor and functional effects of traditional interventions for persons post-stroke have not been supported by research (Dickstein, Hocherman, Pillar, & Shaham, 1986; Kollen, Lennon, Lyons, Wheatley-Smith, Scheper, Buurke, Halfens, Geurts, & Kwakkel, 2009; Luke, Dodd, & Brock, 2004). As the intervention used by a majority of clinics, NDT was the most commonly compared approach. Dickstein et al. (1986) compared the effects of a traditional exercise program, PNF, and NDT interventions on functional gain as measured by Barthel Index, changes in muscle tone, isolated motor control, and ambulatory abilities on 131 persons with acute and sub-acute stroke. None of the three interventions significantly improved these measures. Luke, Dodd, and Brock (2004) systematically reviewed eight studies on the effects of NDT in comparison with other therapeutic approaches for persons post-stroke from 1996 to 2004. Despite insufficient quality of studies, the authors concluded that the evidence tentatively indicated that NDT was not superior to PNF, Brunnstrom, cryotherapy, isolated wrist strengthening, and Motor Relearning on levels of impairment, activity, and participation. Notably, among these approaches, only the wrist strengthening protocol showed significant pre to post assessment improvements in grip strength and activity as measured by the Rivermead Motor Assessment-arm section. Kollen et al. (2009) systematically reviewed 16 RCTs on effects of NDT-based intervention on sensorimotor control, balance, dexterity, mobility, ADL functioning, quality of life, and cost effectiveness of treatment post-stroke. They concluded that, with the exception of balance, NDT-based interventions had no superior effects on any outcomes.

Contemporary Perspectives on Motor Control and Motor Learning

Contemporary theories of motor control and motor learning employ system, ecological, and dynamical theories that acknowledge the influence of environment/context on a person's behavior and believe that the systems of person, task, and environment are heterarchically organized (Mathiowetz & Bass-Haugen, 1994; Shumway-Cook & Woollacott, 2007). Accordingly, task performance emerges from interaction among systems and subsystems. In keeping with this analysis, more current interventions for post-stroke should be client-centered and task-oriented. The primary focus is on functional performance and the secondary focus is on remediating component deficits in strength, ROM, etc. (Mathiowetz & Bass-Haugen, 1994: Mathiowetz, 2016).

Evidence from neuroplasticity studies related to synaptic strength supports perspectives of contemporary theories (Cassidy, Gillick, & Carey, 2014; Murphy & Corbett, 2009). The efficacy of a synapse is inherently influenced by the environment and regulated not only by immediate pre- and postsynaptic activity, but also by the synapse's previous experiences of activity (Bienenstock, Cooper, and Munro, 1982). After stroke, the synaptic-based learning can be used to create compensating circuits for effective and efficient behaviors via homeostatic and Hebbian plasticity regulation mechanisms, respectively (Murphy & Corbett, 2009). The homeostatic plasticity regulates the effectiveness of a behavior by ensuring neurons receive adequate amount of synaptic input, whereas the Hebbian plasticity re-distributes synaptic strength to form a behavioral relevant circuit for efficiency (Murphy & Corbett, 2009). Homeostatic plasticity is

evident after stroke by the formation of new synapses to compensate for lost circuits, but the role of Hebbian plasticity after stroke is unclear (Murphy & Corbett, 2009).

Inter-hemispheric inhibition (IHI) is a mechanism that inhibits the bilateral response within the cortex (Hinder, Schmidt, Garry, & Summers, 2010). A limb's voluntary movements are predominately controlled by the cortex on the contralateral side (e.g., right brain controls left limb). At the same time, the same side of cortex inhibits movement of the ipsilateral limb (e.g., right brain inhibits movement of the right limb). The process of IHI prevents a mirror of UE behaviors and supports accurate motor performance by reducing the size of motor evoked potential produced in the opposite motor cortex (Hinder, Schmidt, Garry & Summers, 2010). Neural activity in the motor areas of both hemispheres is functionally coupled and equally balanced in terms of mutual inhibitory control in healthy brains (Nowak, Grefkes, Ameli, & Fink, 2009). The IHI is related to the intensity of contraction with no significant differences between young and older age (Hinder, Schmidt, Garry, & Summers, 2010) and is more related to distal arm representation (Harris-Love, Perez, Chen, & Cohen, 2007).

Stroke may cause imbalanced interactions of the IHI mechanism across hemispheres (Duque et al., 2005; Nowak, Grefkes, Ameli, & Fink, 2009). Modulation of the IHI in the generation of a voluntary movement may be disrupted when persons post-stroke attempt to move their paretic hand while at the same time the inhibitory responses acting on the paretic hand from the non-affected hemisphere remains (Nowak Grefkes, Ameli, & Fink, 2009). Duque et al. (2005) observed that, compared to healthy controls, the magnitude of IHI in the paretic hand movement is significantly greater in phases of immediately before

movement and around movement onset. Consequently, the affected limb can be doubly disabled (Cassidy, Gillick, & Carey, 2014). Behaviorally, persons post-stroke may demonstrate inefficient and/or reduced use of the more affected limb and may further result in learned nonuse of the limb (Taub, Uswatte, & Elbert, 2002).

Interventions based on the contemporary theories should be task-oriented rather than focused solely on remediating body deficits (Mathiowetz & Bass-Haugen, 1994; Mathiowetz, 2016), and should inhibit the motor areas of the non-affected hemisphere as well as facilitate the motor cortex of the affected hemisphere (Murphy & Corbett, 2009). Together these goals offer ways of rebalancing the inhibitory interactions between the two hemispheres after stroke and to facilitate neuroplasticity within the brain (Nowak et al., 2009; Ward, Brown, Thompson, & Frackowiak, 2003). Corresponding training protocols include the CIMT or modified Constraint-Induced Therapy (mCIT) (Page, Levine, & Leonard, 2005; Page, Levine, Leonard, Szaflarski, & Kissela, 2008; Taub, Uswatte, & Elbert, 2002; Taub et al., 2006; Wolf et al., 2008) and the OTTO approach (Almhdawi et al., 2016; Flinn, 1995; Mathiowetz, 2016). Although Howle (2002) attempted to update NDT theory with contemporary theories of motor control and motor learning, her focus continued to rely on NDT's facilitating movement through therapeutic handling rather than by controlling elements of the task or context during active functional performance. Rao (2014) indicated that it is neither theoretically nor clinically useful to impose the established NDT techniques on new theoretical concepts. Even so, in clinical practice the neurodevelopmental approach remains a commonly used approach to motor training for persons post-stroke (Lennon, Baxter, & Ashburn, 2001).

Research suggests that persons post-stroke would benefit from repetitive practice of the affected limb in task-oriented trainings within the tasks' natural contexts (Nilsen et al., 2015; Urton, Kohia, Davis, & Neill, 2007). The first element is key to CIMT and the first and second elements are both core to OTTO. In a systematic review, Urton and colleagues (2007) reviewed 11 studies of post-stroke interventions. Their findings suggested that goal-directed interventions elicited more typical behavioral patterns in real world situations and that random and blocked practice improve movement performance after intervention. In a second systematic review, Nilsen et al. (2015) found that persons post-stroke appear to benefit more from repetitive task practice, CIMT, strengthening and exercise, mental practice, virtual reality, mirror therapy, and action observation on UE function, mobility and balance, and/or activity and participation. Of these, they further indicated that more effective intervention was associated with repetitive practice of individualized and goal-directed tasks. Practice of tasks that were meaningful to the person especially helped improve motor cortical representation (Bayona, Bitensky, Salter, & Teasell, 2005).

CIMT associates behavioral changes after brain injury to damage in motor control and to the negative consequences of using the less affected limb which lead to suppression and learned nonuse of the affected limb (Taub, Uswatte, & Pidikiti, 1999). CIMT-based intervention uses functional tasks to regain motor function and actual use of the affected limb. CIMT training involves restraint of the more able limb for 90% of the waking day across two-weeks time to create forced use of the more affected limb. That, combined with positive feedback (conditioned response) in successful task performance

(shaping), helps maximize a therapeutic stress on the motor function of the limb (Taub, Uswatte, & Elbert, 2002). During the two weeks, clients receive six hours of daily treatment for a total of 60 hours of therapy in clinic.

Studies of CIMT have demonstrated that persons with mild to moderate stroke develop increased use of the affected limb in real context, better movement quality, and cortical reorganization surrounding the impaired site of the hemisphere (Taub, Uswatte, & Elbert, 2002; Taub et al., 2006; Wu, Chen, Tang, Lin, & Huang, 2007). The therapeutic effects of motor function and actual amount of use were maintained for two years post-treatment (Wolf et al., 2008). Despite this promising evidence, 68% of surveyed persons with stroke expressed an unwillingness to participate in CIMT due to the wear of the restrictive device and concerns about the intensity of CIMT being too fatiguing (Page, Levine, SIsto, Bond, & Johnston, 2002). The same survey also revealed that, 34.1% of surveyed therapists considered CIMT difficult to administer and 65.9% of them were concerned about clients' adherence. This reticence led to studies of mCIT that showed positive effects with as little as 3 hours per week for 10 weeks with the more able limb restricted only 5 hours a day for 5 days/week (Page, Sisto, Levine, and McGrath, 2004). They believed that distributed repetitive practice of clients' valued tasks was more important than the intensity of the practice schedule. The effect of mCIT was reported to be comparable to CIMT for persons with mild stroke who have stroke more than 12 months (Page, Levine, Leonard, Szaflarsiki, & Kissela, 2008).

The OTTO believes that after a stroke a person's use of compensatory strategies reflects his/her attempts for task completion required for the roles (Mathiowetz &

Haugen, 1994; Mathiowetz, 2016). The goal of OTTO is to optimize a person's participation in life via problem-solving strategies of compensation for everyday tasks, and recognition of how ineffective or inefficient motor strategies can be improved to afford greater ease of action (Mathiowetz, 2016). OTTO requires that the therapists understand the person's wants and needs; and identify the critical parameter(s) that have caused the inefficient and ineffective behavioral changes. Intervention strategies may include efforts to remediate the body function (emphasizing increase in strength, range of motion, or evocation of stability/mobility rather than tone), or to adapt the task or environment (Almhdawi et al., 2016; Mathiowetz, 2016). Almhdawi (2011) established OTTO intervention guidelines for persons post-stroke. Almhadawi et al. (2016) reported improved functional performance with therapeutic benefits retained at six weeks post-treatment.

Comparisons between CIMT and OTTO. Both OTTO and CIMT are consistent with the contemporary theories of motor control and motor learning, and while they share some characteristics they differ in several others.

CIMT uses functional tasks as a means for training (Taub, Uswatte, & Elbert, 2002), whereas the OTTO uses functional tasks as a means and as an end (Almhadawi et al., 2016). The CIMT targets at motor acquisition and retention (Taub, Uswatte, & Pidikiti, 1999), whereas the OTTO aims at developing the person's problem-solving capabilities necessary for his/her engagement in tasks required for life roles (Mathiowetz, 2016). This differentiates task selection for intervention and training protocols. The CIMT employs tasks designed specifically for the motor deficits of the person (Taub, Uswatte, & Pidikiti,

1999; Taub et al., 2006). Combined with intensive, repetitive, and massive practice with the more affected limb, the recipients are expected to gradually improve the quality of movements. The OTTO uses client-identified tasks necessary for the client's needs (Mathiowetz & Haugen, 2008; Mathiowetz, 2016). Selected tasks are determined after thorough evaluation and discussion between the therapist and the client. Interventions focus on the critical parameter responsible for behavioral change, which may not be restricted to body function and may change across treatment process (Flinn, 1995; Gillen, 2000; Gillen, 2002; Mathiowetz, 2016).

The two differ in intensity of treatment. CIMT training involves restraint of the more able limb for 90% of the waking day across two weeks to create forced use of the more affected limb (Taub, Uswatte, & Elbert, 2002). However, therapists should be cautious about the intensity and amount of training since adverse effect may occur when overdosed (Cassidy, Gillick, & Carey, 2014). The suggested intensity of OTTO interventions for persons with chronic stroke is three 1-hour/ two 1.5-hour outpatient sessions per week for 6 weeks (total = 18 hours of therapy) working on clients' functional goals and remediating impairments when possible (Almhdawi et al., 2016). This is similar in intensity to mCIT used by Page et al. (2004).

Eligibility for treatment is another major difference between the two approaches. To be eligible for the CIMT or mCIT, potential persons post-stroke are required to have at least 10 degrees of active wrist extension, thumb abduction/extension, & finger extension (Taub, Uswatte, & Pidikiti, 1999). It includes persons with mild to moderate motor difficulties (Fritz, Light, Patterson, Behrman, & Davis, 2005), but excludes those with

more severe motor problems or cognitive challenges (Taub, Uswatte, & Elbert, 2002). OTTO, however, includes persons post-stroke with various challenges, such as more severe motor deficits and/or cognitive challenges, (Almhdawi et al., 2016; Flinn, 1995; Preissner, 2010).

The two approaches also differ in recipients' control of treatment. The CIMT recipients are forced to use the more affected limb in various tasks related to motor deficiencies (primarily unilateral interventions). They have little choice of the tasks of intervention. The OTTO, on the other hand, emphasizes client-centered, occupations-based interventions using unilateral and bilateral tasks, which facilitate self-controlled learning. Self-controlled learning enhances and is significantly and positively associated with self-efficacy and learning (Ste-Marie, Vertes, Law, & Rymal, 2013). Moreover, higher client choice of the tasks used in the intervention process encourages higher adherence rates to therapy (Radomski, 2011).

Re-engagement in the person's life roles should be the ultimate goal for all interventions. The OTTO seems to be more appropriate for typical clinical practice for persons post-stroke due to clients' active involvement; less intensive in clinic; and more distributed training both in clinic and at home (Almhdawi et al., 2016). However, research evidence of its functional effects for stroke population is limited. Additionally, the role of forearm movements in functional training remains unclear.

Effects of the Sole Use of Orthotic Interventions for Persons Post-Stroke

Most orthotic designs for persons post-stroke are forearm based and meant to immobilize wrist and/or hand and target at impairment level with goals of inhibiting

spasticity and preventing ROM limitations (Gillen, 2016). Orthoses are used in the neurophysiological approach to inhibit reflexes, control flaccid, and/or spastic muscle tone, and improve agonist-antagonist balance, and in the biomechanical approach to maintain or correct joint alignment. Some orthoses are also used to assist performance of functional tasks and (compensation approach) (Gillen 2016). In addition, a single design may serve multiple purposes (Gillen, 2016). For example, due to the close relationship between spasticity and joint deformity/muscle tightness, an immobilization wrist orthosis can be used to stabilize the wrist and to allow more effective functional hand use (Burtner, Poole, Medora, Abeyta, Keene, & Qualls, 2008). However, orthotic application for stroke population has always been controversial because of the multiple theories associated with orthotic use, the diversity of orthotic designs and the complexity of stroke (Lannin & Herbert, 2003; Gillen, 2016; Steultjens et al., 2003).

There is little rigorous research on the effects of orthoses for persons post-stroke. Lannin and Herbert (2003) tried to systematically review the effectiveness of orthotic intervention for persons post-stroke in 19 studies (4 randomized controlled trials, 11 case series studies, 2 case studies, and 2 non-randomized studies). Since these studies involved different orthotic designs and lacked rigorous designs, they were unable to conclude any positive or negative effects on motor control, functional abilities, contracture, spasticity, or pain. Tyson and Kent (2011) conducted a meta-analysis of 4 RCTs of UE orthotics for persons post-brain injury. With pooled sample size of 126 participants, they examined the effects of overnight wear of a custom-made, forearm-based, wrist, finger, and/or thumb thermoplastic orthosis on UE function (measured by Motor Assessment Scale), passive

ROM of wrist, finger and thumb, spasticity of affected wrist and fingers, and pain at the wrist. They found that the orthosis had no significant effect on any of the outcome measures.

Most evidence does not support neurophysiological-based orthotic interventions that focus on spasticity reduction (Basaran, Emre, Karadavut, Balbaloglu, & Bulmus, 2012; Jung et al., 2011; Steultjens et al., 2003). There were no effects on spasticity at wrist and finger flexors when positioned in resting position for 2 minutes (Mathiowetz, Bolding, & Trombly, 1983), for two hours (Mills, 1984) measured by EMG recording, for four weeks measured by the Tardieu Scale (Lannin, Cusick, McCluskey, & Herbert, 2007), and for five weeks measured by the Modified Ashworth Scale (Basaran et al., 2012). However, positioning the wrist and hand in resting position for three months resulted in spasticity reduction at elbow flexors as measured by the Modified Ashworth Scale (Pizzi, Carlucci, Falsini, & Verdesca, 2005). There was no effect on spasticity at wrist and finger flexor when positioning the finger in abduction for 2 minutes (Mathiowetz, Bolding, & Trombly, 1983). Jung et al. (2011) reported significant improvement on spasticity when wrist and finger flexors were stretched into full extension for 20 minutes, twice per day for three weeks as measured by the Modified Ashworth Scale. However, there was significant regression one week after the stretching program was discontinued. It is not clear if spasticity would return to baseline without continued stretching. In contrast, Lannin et al. (2007) found neither clinically nor statistically improvement when worn 12 hours overnight for four weeks.

Most evidence does not support biomechanical-based orthotic interventions that focus on ROM (Lannin, Horsley, Herbert, McCluskey, & Cusick, 2003; Lannin et al., 2007; Pizzi et al., 2005). No significant improvement on passive ROM at wrist was found when positioned the wrist at neutral or 45 degrees of extension for four weeks (Lannin et al., 2007). No significant improvement on passive ROM at wrist was found when positioned the wrist and hand in resting position for 4 weeks (Lannin et al., 2003) or for 5 weeks (Basaran et al, 2012). In contrast, wearing the orthosis for three months, Pizzi et al. (2005) found significant improvement in wrist passive ROM in extension (14 degrees) with placing the wrist and hand in resting position.

A restriction orthosis allowing limited movement of the splinted body segment may facilitate motor performance. Compared to a volar wrist immobilization orthosis and no orthosis, Burtner et al. (2008) found that children with a spastic arm showed greater muscle strength and dexterity with a spiral forearm-wrist restriction thermoplastic orthosis that allows 30 degrees of wrist movement. Their findings suggest the use of the restriction orthosis to improve functional hand use in terms of less performance time. However, the design is difficult to put on for persons with a spastic arm and may reduce orthotic adherence.

In summary both neurophysiological- and biomechanical-based orthotic interventions target impairment levels. Even with these non-functional goals, the evidence does not support sole use of orthoses for persons post-stroke for either reducing spasticity or maintaining the length of soft tissues. In addition, no study examined whether or not improved passive ROM of splinted body parts leads to functional

improvement. Researchers (Burtner et al., 2008; Pereira, Thambyah, & Lee, 2012), who considered the effect of immobilization wrist orthoses on compensatory movement found that with enhance functional hand use came excessive shoulder and trunk movement or amplified shoulder muscle activity on the involved limb (Mell, Childress, & Hughes, 2005; Mell, Friedman, Hughes, & Carpenter, 2006). This suggests that use of immobilization orthosis as the sole intervention for persons post-stroke has no direct positive effects on improvement of impairments. When using an immobilization orthosis to facilitate functional use of the affected limb, therapists should be cautious for inducing unwanted compensatory movements of the affected limb.

Effects of Orthotic Interventions Combined with Other Treatments for Persons Post-Stroke

When orthoses are combined with other treatments to facilitate change, the effects can become more pronounced. Some researchers (Dunning, Berberich, Mortelite, Levine, Hermann, & Page, 2008; Shindo, Fujiwara, Hara, Oba, Hotta, Tsuji, Hase, & Liu, 2011) proposed a therapeutic regimen that combines an immobilization wrist orthosis as passive modality with neuromuscular electrical stimulation on wrist and finger muscles in conjunction of task-specific training for persons post-stroke and for children with cerebral palsy. The immobilization orthosis was only worn during functional training. This regimen has shown immediate positive effects in improvements in motor function of UE measured by Action Research Arm Test and Fugl-Myer Scale for persons post-stroke (Dunning et al., 2008; Shindo et al., 2011) as well as improved hand skills measured by Abihand-kids test for children with cerebral palsy (Yildizgoren, Yuzer, Ekiz, & Ozgirgin,

2014). Hardy et al. (2010), on the other hand, used this regime with an immobilization orthosis that locked the elbow, wrist, and fingers on one person with chronic stroke. Although they found improvement in UE motor function, no statistical comparison was reported. Additionally, only one study measured and reported insignificant improvement in actual use of the affected limb measured by the Motor Activity Log (Shindo et al., 2011).

Significant improvement in motor function (measured by the Fugl-Meyer Scale) was also reported when employs the same regime with a mobilization orthosis for persons post-stroke (Butler, Blanton, Rowe, & Wolf, 2006; Farrel, Hoffman, Snyder, Giuliani, & Bohannon, 2007; Hoffman & Blackey, 2011). Butler et al. (2006) and Farrel et al. (2007) used a finger and thumb mobilization orthosis (SaeboFlex) combined with neuromuscular electrical stimulation and intensive task-specific training for one and 13 persons with chronic stroke, respectively. They demonstrated significant effects of this regime in improved active ROM at shoulder and elbow as well as UE motor function measured by the Fugl-Meyer Scale. This regime is consistent with the contemporary theory of motor control that emphasizes practice and active functional hand use. The SaeboFlex uses spring assistance to enable users to open their hand, but the users' forearm is restricted in pronation. It is designed to assist in hand opening during functional tasks. However, its design, such as high profile design, difficult to put on, and sensory input blocked by the volar pads of the fingers, may influence clients' willingness to use the orthosis. Moreover, restricting forearm movements during functional tasks is contraindicated based on lab and clinical findings of functional hand use (Braendvik, Elvrum, Vereijken,

& Roeleveld, 2010; Mackey, Walt, & Stott, 2006; Pereira, Thambyah, & Lee, 2012; Safaee-Rad, Shedyk, Quanbury, & Cooper, 1990; van Andel, Wolterbeek, Doorenbosch, Veeger, & Harlaar, 2008).

When a mobilization orthosis is combined with functional training, more effective and efficient use of the hemiparetic arm can be expected. Lee, LaStayo, and von Kersburg (2003) indicated that incorporating a mobilization orthosis in active training could be seen as a "passive modality" (p. 194) to increase active ROM. A mobilization orthosis can be used to assist or enhance functional hand use during functional tasks (Dunning et al., 2008; Farrell, Hoffman, Snyder, Guiliani, & Bohannon, 2007; Hoffman & Blakey, 2011; Lannin & Ada, 2011; Pitts & O'Brien, 2008). While the goal is to facilitate task performance, an appropriate orthotic design for stroke population should reflect the dynamic nature of motor control.

Feasible Orthotic Design and Rationale for Orthotic Use with Current Theories

As with all occupational therapy, orthotic intervention used in treatment should be client-centered to gain fullest adherence, occupation-based, and geared to optimize functional performance (McKee & Rivard, 2004). Thus, occupational therapists need to consider a client's valued occupations as well as factors influencing orthosis adherence (e.g., client's comfort, orthotic aesthetics, convenience, need for follow-up) and facilitation of function (e.g., principles of least restriction and lightest design) (McKee & Rivard, 2004). Using occupation-based approach allows therapists to focus their interventions on functional performance rather than on the change in the impairment

level. As a result, occupations can be used both as a means and an end (Coppard, 2008; Mckee & Rivard, 2004).

The OTTO approach appears to be a compatible intervention to combine with orthotic use for persons post-stroke to enhance functional use of the hemiparetic limb, and to optimize functional outcomes. Identifying the critical control parameter(s) that influence this behavioral change and working on that/those identified system(s) are key to making the dual approach efficient and effective for clinical use. However, this approach has not been studied with forearm rotation orthosis used for persons post-stroke.

Forearm rotation is currently not emphasized in clinical intervention post-stroke. Given the evidence of high correlation between active forearm rotation and overall UE muscle strength and motor function (Braendvik, Elvrum, Vereijken, & Roeleveld, 2010), it is surprising that there has been little study of the potential impact of treatment aimed at that motion. The proposed study examined the effects of a lightweight, low profile forearm rotation mobilization orthosis that is easily donned and doffed with one hand, and assists functional training. Guided by the OTTO, when body function, specifically weak forearm movements, are identified as the critical control parameter, users may benefit from such an orthosis as one anti-gravity assistance modality for forearm movements. Combined with functional training, improvement in task performance can be expected. This study hopes to begin to examine one possible way to incorporate a hands-off orthosis to enhance motor control and functional performance.

Purpose

The purposes of this study were to examine the efficacy of a forearm rotation orthosis alone and when combined with the OTTO approach as well as to evaluate the efficacy of the OTTO approach on functional performance and impairments for persons with a hemiparetic arm. "Functional performance" represents improvement in occupational performance as measured by the *Canadian Occupational Performance Measure* (COPM), *Motor Activity Log* (MAL), and the *Wolf Motor Function Test* (WMFT). "Impairments" of muscle weakness were measured by dynamometers and pinch gauge and of limited AROM were measured by goniometers. Study hypotheses were 1) participants who received the forearm rotation orthosis as the sole intervention would demonstrate no greater improvements in functional performance and impairments than those with no treatment at the end of the orthosis only phase (posttest 1); 2) participants who received the OTTO intervention both as sole intervention and in combination with the orthosis would demonstrate significant improvement in functional performance and in active ROM and strength of the UE measured by goniometry, JAMAR dynamometer, and pinch gauge; 3) participants who received the OTTO intervention in combination with the orthosis would demonstrate significantly greater improvement in functional performance and impairments by the end of participation (posttest 2) than those who received OTTO intervention as sole intervention (posttest 2). Finally, it was expected that participants would have at least 80% adherence to the orthotic wearing both at the clinic and at home.

The study results will assist refining the application guidelines of the OTTO approach for persons post-stroke as well as adding evidence of its efficacy. In addition, the study results may help therapists understand the important role of the forearm rotation in rehabilitation that could benefit clients and therapists.

Method

Research Design

The study employed a matched, randomized, two- group, single-blinded, repeated measures design (Table 1). An internal pilot study was used in this study (Wittes & Brittain, 1990). Wittes and Brittain (1990) suggested that when the study design and procedure remain unchanged or require slight modification, such a design allowed all obtained data from the pilot study to be included in the main study's analyses.

Table 1.

Experimental design of the pilot study

Group/Week	Week 1	Week 2-7	Week 8	Week 9-14	Week 15
M R A	O1	Orthosis	O2	Orthosis+OTTO	O3
M R B	O1	No Tx	O2	OTTO	O3

Note. M=matched with severity of motor function; R = random assignment; O1,2,3 = time points for outcomes measures; No Tx = six weeks of no treatment; Orthosis = six weeks of forearm rotation orthotic intervention; OTTO = six weeks of OTTO approach intervention.

Eligible participants were first matched for severity of motor function impairment based on UE subscale of the *Short Form of the Fugl-Myer Motor Function Assessment* (S-FM). Participants were classified as severe (scored 3-5), moderate (scored 6-8), and

mild (scored 9-11) groups. Participants in each group were then randomized in a 1 to 1 ratio to either Group A or B using sealed envelopes with an equal number of both intervention conditions to balance group size (10 for each matched group with 5 in Group A and B, respectively). Outcome measures were assessed before and after each experimental condition. Five student therapists blinded to the content of the experimental conditions assessed the outcome measures for all participants. However, the interventionist administered the COPM, because identified functional tasks were critical component of the OTTO approach. It was not possible to blind participants to the intervention that they were receiving. The independent variables of the study were intervention: use of the orthotic intervention only, orthosis plus OTTO intervention, OTTO intervention only, and no intervention

Participants

Persons with one hemiparetic arm secondary to stroke were recruited from the Twin Cities metropolitan area through advertising via flyers in local hospitals (i.e., University of Minnesota Medical Center, Fairview hospitals, Hennepin County Medical Center, the North Memorial Hospital), The Minnesota State Fair, the Minnesota Stroke Association (Newsletter and Facebook page), and flyers sent to previous stroke volunteers at OT onsite clinic at the University of Puget Sound.

To be included participants had to 1) have a diagnosis of stroke for at least three months, 2) be 18 years of age or older, 3) sufficient cognitive function to follow three-step verbal instruction, provide independent consent, and score at least 24 on the Mini Mental Status Examination (MMSE), 4) have trunk and lower extremity function that did

not interfere with use of the upper extremity in functional tasks (at least 4 points in the LE subscale of the S-FM), and 5) have minimum voluntary movement in the upper extremity of at least 10 degrees of shoulder flexion/abduction, 10 degrees of elbow flexion/extension and at least 3 points in the UE subscale of S-FM. Participants who regularly received pharmacological treatment(s) or Botox injection for spasticity management prior to the study were asked to continue their regimen. Effect of spasticity management was monitored as a potential intervening variable.

The S-FM was employed to screen motor function of the upper and lower extremities (Hsieh et al., 2007). The SFM uses 6-items from the upper and lower extremity subscales of FMA, respectively. Administration of the S-FM scale requires approximately 10 minutes. Eligible participants needed to have at least 3 points in the upper extremity subscale and at least 4 points in the lower extremity subscale. Hsieh et al. (2007) reported that the S-FM has good concurrent reliability ($r \geq .93$) with the original version of *Fugl-Meyer* assessment and moderate predictive validity ($r = .49$ to $.59$) with the comprehensive activities of daily living function (combination of the Barthel Index and the Frenchay Activities Index). Good predictive validity ($r = .68$) between the S-FM and the streamlined *Fugl-Meyer Assessment* were also reported (Fu et al., 2011).

The MMSE was used to evaluate overall cognitive function (Crum, Anthony, Bassett, & Folstein, 1993). It is a standardized screen of cognitive function consisting of items on orientation, attention, immediate and short-term memory, language, and the ability to follow simple verbal and written commands. Sixty-nine percent sensitivity and 99% of specificity were reported (Tangalos et al., 1996).

Exclusion criteria included 1) severe joint deformities or contractures of the affected upper extremity that limit ROM required for functional tasks, 2) capability of voluntarily extending the wrist and fingers through the full range or scored 12 points in the UE subscale of S-FM, 3) participating in any other rehabilitation interventions concurrent with the study, and 4) serious uncontrolled medical problems, such as seizures or visual impairment.

Interventions

There were four intervention groups:

No treatment. Participants in the Group B first underwent a no treatment condition period during which they were asked to maintain their current activity level. They were required to wear the Nike+FuelBand (Figure 1) to monitor their use of the affected arm throughout the study. The investigator made 6 weekly phone calls to remind them to recharge the wristband and facilitate adherence to the study.

Figure 1. Nike+FuelBand used in the study to monitor participants' use of the affected arm.

OTTO intervention. Participants in the Group B then experienced a second 6 weeks of OTTO intervention. The OTTO intervention consisted of 18 hours of intervention time (three 1-hour or two 1.5-hour clinical sessions per week for 6 weeks). Each session focused on engaging the affected arm actively, effectively and efficiently in functional motor tasks that were meaningful to the participant.

Study use of OTTO approach followed the general guidelines for evaluation and intervention developed by Mathiowetz (2016) and Almhdawi et al. (2016). Each participant's occupational profile was developed at the first week of intervention using *Role Checklist, Interest Checklist,* and COPM (Appendix A-C). This information allows activity analyses of the task, person and environment, to identify the potential *critical control parameter(s)* (i.e., performance component and/or performance context) that influence functional performance.

After the critical control parameter(s) was identified, each participant's motor behavior was identified as:

- In *transition* or behavior is responsive for improvement, when remedial strategies, such as ROM, endurance, and muscle strengthening, were employed.
- In fixed or more established movement patterns, when adaptation/compensatory strategies, such as adaptive devices or task simplification, were used to allow functional performance.
- Both remedial and compensatory strategies may be used at the same time to optimize functional performance.

In addition to developing effective and efficient motor behaviors for the clinical tasks, each session focused on developing a participant's problem solving capabilities for everyday life. Only as a secondary focus was treatment targeted directly at client factors or impairments that limited functional performance. In each session of OTTO intervention, a participant engaged in functional tasks by managing the degrees of freedom on any or all identified controlling systems. For example, a mobile arm support was used to assist shoulder movement against gravity and allow easier elbow movements during a feeding task.

The selection of functional tasks were derived from both the COPM and those identified in the *Interest Checklist* or mentioned during interview as being problematic tasks that a participant encountered in real life. As their home program, participants were asked to apply these same learned strategies in real life. Because the critical control parameters may change over time (Flinn, 1995), participants' functional performance was assessed at each session and the intervention adjusted accordingly.

Forearm rotation orthotic intervention. The study's forearm rotation orthosis (Figure 2) consisted of a commercial fabric wrist orthosis (Wrist Lacer™, Medical Specialist, Inc.), and a Latex-free neoprene strap, which assisted forearm rotation without limiting functional elbow flexion and extension. During the orthotic phase, participants were encouraged to wear the orthosis daily during functional tasks. The investigator made six weekly phone calls during this period to enhance orthotic adherence. To maintain blinding of the assessor, participants were asked not to bring the orthosis to evaluation sessions. Information regarding possible risks of use of the orthosis was

included in the consent form (UMN IRB# 1309M42881) as well as the written instructions (Appendix D).

Figure 2. The forearm rotation orthosis.

Forearm rotation orthotic intervention plus OTTO approach. Participants in Group A experienced a 6 weeks of orthosis plus OTTO intervention after 6 weeks of orthotic intervention only. The protocols used during solo interventions were also used when the two interventions were used in combination.

Study Outcomes/Endpoints

Five blinded evaluators collected data at three time points throughout the study (pretest 1, posttest 1, and posttest 2; Table 1). Assessments were performed within the scheduled 2-hour session.

The primary endpoint for the study was functional performance as assessed by an improved score in the Canadian Occupational Performance Measure, the Wolf Motor Function Test, and the Motor Activity Log. The secondary endpoints were increased AROM and muscle strength of shoulder flexion/abduction, elbow extension, forearm

pronation/supination, and wrist extension, increased grip and pinch of the involved UE as well as adherence with orthosis.

Functional Performance Outcomes

Canadian Occupational Performance Measure (COPM). The COPM (Law, Baptise, Carswell, McColl, Polatajko, & Pollock, 2005) was employed to measure a participant's perceptions of current task performance and satisfaction with the performance. It is a semi-structured interview requiring a participant to identify the importance of, perception of, and satisfaction with performance in areas of ADL, productivity, and leisure on a scale ranging from 1 to 10. When the top five ranked meaningful functional tasks were determined, these tasks were used to guide intervention and examine changes in client perception. The test-retest reliability of COPM is high (r = .89 for performance scores; r = .88 for satisfaction scores) and discriminant validity is confirmed in stroke patients (Cup, Reimer, Thijssen, & van Kuyk-Minis, 2003). The Investigator administered the COPM as the gathered information was used to develop treatment plan. Administration of the measure took about 20 to 40 minutes.

Wolf Motor Function Test (WMFT). The WMFT (Wolf et al., 2001) was used to quantitatively measure the participant's UE motor ability using timed and functional tasks. The WMFT consists of 15 items. The first 6 items measure timed joint-segment movements, such as forearm to table, extend elbow, and hand to box, and the remaining eight items evaluate timed integrative functional movements, such as lift can, pick up paper clip, and turning the key in lock. The WMFT uses six-point ordinal scale (0 = does not attempt with the involved arm, 5 = arm does participate; movement appears to be

normal). Discriminant validity was established between normal participants and persons with stroke (Wolf et al., 2001). Inter-rater reliability (r = 0.97 or greater for performance time, r = 0.88 or greater for functional ability) and test-retest reliability (r = 0.90 for performance time, r = 0.95 for functional ability) was established (Morris, Uswatte, Crago, Cook, & Taub, 2001). Administration time was about 35 minutes.

Motor Activity Log (MAL). The MAL (Taub et al., 1993) was used to measure actual use of the affected arm in the real world. The MAL is a structured interview that the respondents are asked to rate how well (Quality of Movement scale) and how much (Amount of Use scale) they use the affected arm to accomplish 30 ADL and IADL tasks. The test uses 6 hierarchical points (0 = never used, 5 = same as pre-stroke) to rate the corresponding status. Respondents may select scores halfway between the two points that best reflects the status. Test-retest reliability (r = .82) and validity (correlation between Quality of Movement and Stroke Impact Scale, r = .72; correlation between participant Quality of Movement and Amount of Use, r = .92) of the measure was supported (Uswatte, Taub, Morris, Light, & Thompson, 2006). Administration of the measure was 20-30 minutes.

Impairment Outcomes

Active range of motion (ROM). Goniometric measurements were obtained in degrees to calculate passive and active ROM. Results of measurement of active and passive ROM of the UE were used to determine possible factors that cause limitation. When measured passive ROM was greater than the active ROM, it indicated muscle weakness. When limitation in passive ROM was found, it indicated problems in passive

motion. The study measured the functional active ROM and passive ROM, including shoulder flexion/abduction, elbow extension, forearm supination/pronation, and wrist extension. Intra- and inter-rater reliability were reported strong (ICC: .91 and .75, respectively) (Gouveia, Araujo, Maciel, Ferreira, & Santos, 2014). Administration of the measure was about 15 minutes.

Upper extremity strength. Muscle strength of shoulder flexion/abduction, elbow extension, forearm pronation/supination, and wrist extension were recorded through the hand-held dynamometry. The hand-held dynamometry is reliable for objectively detecting small changes in strength of isometric muscle contraction (Bohannon, 1986; Ottenbacher et al., 2002; Phillips, Lo, & Mastaglia, 2000). Bohanon (1986) reported that when executed by an experienced clinician, the test-retest reliability for all muscle groups ranged from .84 to .99 ($p < .01$). Ottenbacher et al. (2002) reported excellent test-retest reliability (ICC raged from .74 to .96 for 27 lay raters on one subject and from .87 to .98 for 12 lay raters on 63 participants) of the hand-held dynamometry on 63 older adults (mean age of 70.51 $\pm$ 4.73) when the examiners received a two-day intensive training on administering muscle testing. In a study examining the intra-session and inter-session reliability on five upper extremity muscle groups and two lower extremity muscle groups using a hand-held dynamometer on 200 healthy participants, Phillips, Lo, and Mastaglia (2000) reported excellent intra-session (three consecutive test with five-second interval) reliability (ICC > .95) and good inter-session (two weeks interval) reliability (ICC > .85) for overall muscle groups. The study used the "break" testing method described by Phillips et al. (2000) with sitting position while testing (Almhdawi, 2011) for hand-held

dynamometry for both upper extremities. The "break" testing method required the examiner to exert sufficient force to break the tested position held by the participant (Phillips, Lo, & Mastaglia, 2000). Study participants needed to perform three consecutive trials with one minute resting time between trials. The average force of each tested position was used for analysis. Administration of both measures was about 15 to 20 minutes.

Grip and pinch strength. A calibrated Jamar Dynamometer was used to measure grip strength in pounds. A B & L Engineering pinch gauge was used to measure palmar pinch and lateral pinch strength in pounds. Measurements followed the standardized positions and instructions suggested by Mathiowetz et al. (1985). Measurements of the hand-held grip dynamometry (Jamar) were reported highly correlated with the MMT of upper extremity strength in home care patients (r_s = .421-.848; r = .537-.799; R = .589-.934) (Bohannon, 1998). Administration of both measures was about 5 to 10 minutes.

Orthosis adherence. All participants wore the Nike+ FuelBand at the wrist level throughout the study period and were informed that the wristband was used to monitor their use of the arms during a day. Participants experiencing the orthotic intervention (Group A) wore the forearm rotation orthosis on top of the wristband. All participants received weekly phone calls from the investigator reminding them to recharge Nike+ FuelBand since it needs to be recharged by connecting to a computer or any device with a USB port every 4-7 days and to wear their forearm orthosis during functional tasks. It was assumed that wearing of the Nike+ FuelBand would indicate wearing of the orthosis. The investigator gathered Nike+ FuelBand data at posttest 1 and posttest 2.

Intervention fidelity

Interventionist. The investigator was the primary interventionist providing OTTO intervention for all participants. He developed treatment plans for all participants based on the COPM. Dr. Virgil Mathiowetz, the theorist behind the OTTO approach and the academic advisor, worked closely and regularly with the investigator to ensure fidelity to the OTTO approach and to monitor safety during the study period.

Blinded evaluators. Five occupational therapy students served as blinded evaluators for this study- three from the University of Minnesota and two from the University of Puget Sound. Every blinded evaluator conducted all evaluations except the COPM for the same participant. The investigator worked with all evaluators to develop inter-rater reliability. Agreement rate of 99% was reached within 8 hours. They then implemented the WMFT, MAL, AROM, and strength assessments.

Procedures

After obtaining IRB approvals from the University of Minnesota and the North Memorial Hospital, a preliminary study of four participants (two for each arm) was completed to examine the feasibility and to improve the design of the full-scale study. IRB approval from the University of Puget Sound was also obtained since no change in study protocol was determined after the preliminary study.

Volunteers were recruited through posting flyers in local hospitals and at Minnesota State Fair, on the website of Minnesota Stroke Association, and mailed to volunteers for the OT onsite clinic at the University of Puget Sound (Appendix E for flyer). Interested persons contacted the investigator for more detailed information. Oral consent was

obtained and the screening session was scheduled when they appeared to meet the inclusion criteria. The investigator administered screening tools, including MMSE, S-FM, and passive and active ROM, cognitive function, motor function, and possible movement limitation for inclusive and exclusive criteria. Eligible participants were informed of the purposes of the study. After making sure the participants understand and were willing to participate in the study, the consent form (Appendix F) was discussed. Each eligible participant had at least one week to consider his/her participation in the study. The participants were matched with severity of motor function and then randomly assigned using sealed envelopes with an equal number of both intervention conditions to balance group size after written consents were obtained (Table 1 and Figure 3).

The investigator fabricated the forearm rotation orthosis for participants in Group A. The six-week orthotic intervention began after orthosis fabrication. Participants were required to wear the orthosis on top of the Nike+FuelBand.

Participants in Group A received 6 weeks of orthotic intervention followed by another 6 weeks of orthosis plus OTTO intervention. Participants in Group B first experienced 6 weeks of no treatment followed by 6 weeks of OTTO intervention. A blinded evaluator administered primary and secondary outcome measures for each participant before and after the experimental condition. The investigator administered the COPM for development of treatment plan.

Data Management

All information collected from the Twin Cities area was kept within a locked file cabinet in the rehabilitation science graduate student office, which requires security code

for access. Subject's name and contact information were kept in a separate file from the data gathered from the study using an ID code. Personnel from the department have access to the office. However, only the investigator has access to locked file cabinet. Data collected from this study will be maintained for three years after completion.

All information collected from the OT onsite clinic at the University of Puget Sound was converted into digital files and uploaded within 24 hours to the "Box" secure storage operated by the University of Minnesota. The "Box" is an online storage space that allows storing Protected Health Information. Only the investigator has the access to "Box" as it requires duo-factor authentication to log in. Information on the "Box" is at http://box.umn.edu. After converting, all printed documents were shredded. All identifying materials such as the consent forms were kept in a locked file in the Occupational Therapy Department at the University of Puget Sound, WEY 106. Data collected at the University of Puget Sound will be maintained for three years after completion of the study, and then shredded.

Data Analyses

Data analyses were performed using R software (version 3.4.3) (R Core Team, 2017). Normality of variables was examined graphically with variation bands using the "sm" package (Bowman & Azzalini, 2014). Descriptive statistics were used to characterize the demographic data, baseline information, and adherence with orthosis wearing.

A linear mixed-effects model from the "lme4" package (Bates, Maechler, & Bolker, 2012) was used to compare the effects across time with and without an orthosis. When

compared to analyses of repeated measures using analysis of variance (ANOVA), covariance (ANCOVA), or multivariate (MANOVA), a mixed-effects model has greater flexibility to clarify effects across time, greater statistical power to find differences, and less risk of the Type I error (Gueorguieva & Krystal, 2004). The *systematic fixed effects* of the study were *group* and *time*. *Study participants* were the *random factor* and were added into the model to control for their associated intraclass correlation (ICC) (Pinheiro & Bates, 2000). The *p* values of all linear mixed-effects models were obtained using the "lmerTest" package (Kuznetsova, Brockhoff, and Christensen, 2017).

After Bonferroni adjustment, a significance level of .017 was set a priori for primary functional outcome measures, with $p < .008$ set for UE AROM and strength; and $p < .017$ set for grip and palmar and lateral pinch strengths. By default, the original mixed-effects model used the pretest as a reference for comparisons between pretest and posttest 1 and between pretest and posttest 2. When significant differences between pretest and posttest 2 values were detected, a second linear mixed-effect model was performed with the pretest as the covariate reference to examine effects between posttest 1 and 2.

Results

Data Description

It was difficult to acquire study participants, so two different sites were used: Minneapolis and St. Paul metro area in Minnesota and Tacoma, Washington. Recruitment was active from December 2015 to January 2018. Twenty persons post-stroke were screened. Of these, 18 were eligible and included after written consent was given (UMN IRB# 1309M42881, UPS IRB# 1617-002-1; Appendix F). Two interested persons were

excluded, both due to S-FM scores that 1) one scored higher than 11 and 2) one scored lower than 3.

After matching participants' levels on the S-FM, ten participants were randomly assigned to Group A and eight were assigned to Group B. Four participants left the study before their posttest 1 (2 from each group, with a total attrition rate of 22%). In Group A, one participant dropped because of lost transportation and one due to a heart attack of his caregiver. In Group B one left due to a recurrence of severe shoulder pain that had been present before the study and one lost interest in the study. Eight in Group A and six in Group B completed the study (Figure 3). Participants who dropped the study and those who completed the study were not significantly different in any of the demographic, primary outcome, and secondary outcome variables (i.e., gender, age, level of motor function severity, distribution across ethnic groups, pre-stroke dominant hand, post-stroke less affected hand, stroke type, months post onset, current spasticity treatment, education level, and current employment status, overall performance and satisfaction on the COPM, performance time and functionality on the WMFT, and amount of use and quality of use on the MAL, ROM and strength of UE, grip, and pinch).

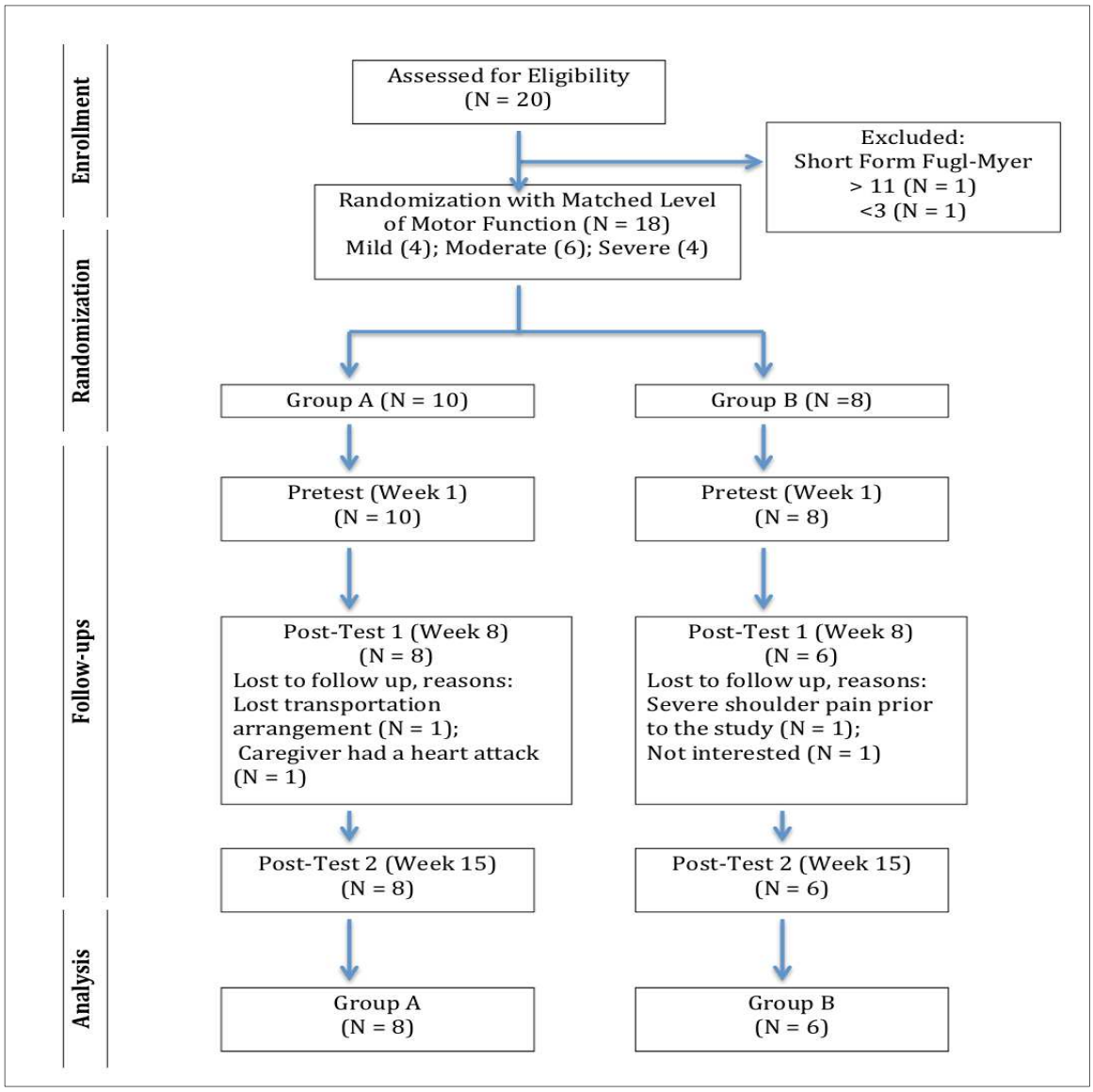

Figure 3. Flow chart of study participants throughout the study.

Group characteristics. Due to the study's small sample size, nonparametric methods were used for comparison of the demographic information. The Fisher's exact test was used to examine categorical data such as gender and level of motor function severity, and the Mann-Whitney U test was used for numerical data, such as age and

months post onset. Table 2 indicates the groups' descriptive characteristics distribution and the *p* value of their comparisons.

Table 2.

Demographic Information

Variables	Group A	Group B	*p*
Gender			1.0
Male	6	5	
Female	2	1	
Age, Mean (SD)	53.88 (11.99)	58.5 (10.17)	.80
Severity			1.0
Mild	2	2	
Moderate	4	2	
Severe	2	2	
Ethnicity			.47
White	6	6	
Asian	2	0	
Dominant hand (pre-stroke)			
Right	8	6	
Left	0	0	
Hand Affected			.25
Right	1	3	
Left	7	3	
Stroke Type			.63
Hemorrhagic	4	2	
Ischemic	4	4	
Months post onset	8-102	12-68	.60
Mean (SD)	57.38 (29.38)	47.5 (23.49)	
Current Spasticity Treatment			.30
Yes	4	5	
No	4	1	
Education Level			1.0
Less than 12 years	2	2	
12-15 years	3	2	
More than 15 years	3	2	
Employment Status			.24
Part time (20-39 hours)	2	1	
Part time (1-19 hours)	2	1	
Unemployed (disability)	4	1	
Retired	0	3	

Note. SD = standard deviation; Level of significance: $p < .05$

The two groups were not significantly different in any of the variables (i.e., gender, age, level of motor function severity, distribution across ethnic groups, pre-stroke dominant hand, post-stroke less affected hand, stroke type, months post onset, current spasticity treatment, education level, and current employment status). Therefore, none of the demographic variables was added as a covariate when comparing the effects of orthotic intervention, OTTO intervention, separate or in combination.

Primary and secondary outcome measures. Table 3, 4, and 5 indicate mean and standard deviation for primary and secondary outcome variables for Group A and B across time, respectively. Density plots for each primary outcome variable at each time point (i.e., COPM, WMFT, self-reported amount of use of the affected limb, and self-perceived quality of performance according to the MAL) were examined visually for normality. Pretest, posttest 1, and posttest 2 were each within the variation bands, suggesting that all were normally distributed. All secondary outcome variables in both groups appeared to be normally distributed examined by the variation band.

Table 3.

Mean and standard deviation (SD) for primary outcome variables for Group A and B across pretest, posttest 1 and posttest 2 (N = 14)

Variables	Group A Mean (SD)	Group B Mean (SD)
COPM		
Performance		
Pretest	2.95 (.77)	3.77 (1.33)
Posttest 1	3.30 (1.21)	3.43 (1.05)
Posttest 2	5.80 (1.34)	5.98 (1.53)
Satisfaction		
Pretest	2.73 (1.11)	3.17 (1.48)
Posttest 1	3.18 (1.54)	3.10 (1.18)
Posttest 2	5.93 (1.19)	5.65 (1.29)
WMFT		
Performance Time (second)		

Pretest	66.25 (17.99)	40.38 (40.45)
Posttest 1	63.25 (14.88)	39.15 (39.49)
Posttest 2	61.41 (15.57)	44.65 (39.36)
Function		
Pretest	2.07 (.35)	2.8 (.94)
Posttest 1	2.16 (.42)	2.77 (1.33)
Posttest 2	2.16 (.36)	2.9 (1.33)
MAL		
Amount of use		
Pretest	.46 (.42)	1.06 (.85)
Posttest 1	.56 (.57)	1.01 (.96)
Posttest 2	.81 (.64)	1.61 (1.22)
How well		
Pretest	.52 (.47)	1.15 (.75)
Posttest 1	.56 (.54)	1.18 (1.19)
Posttest 2	.86 (.66)	1.63 (1.20)

Note. COPM = Canadian Occupational Performance Measure; MAL = Motor Activity Log; SD = standard deviation; WMFT = Wolf Motor Function Test.

Table 4.

Mean and standard deviation (SD) for AROM across pretest, posttest 1, and posttest 2 (N = 14)

Joint Movements	Group A Mean (SD)	Group B Mean (SD)
Shoulder flexion		
Pretest	103.5 (30.56)	99 (41.91)
Posttest 1	92.75 (33.52)	93 (29.15)
Posttest 2	100.38 (38.06)	96 (29.5)
Shoulder abduction		
Pretest	96 (33.56)	95.17 (32.33)
Posttest 1	85.75 (25.27)	87.83 (26.28)
Posttest 2	87.75 (31.35)	90.33 (27.34)
Elbow extension		
Pretest	117.25 (17.52)	103.67 (33.21)
Posttest 1	113.13 (21.01)	97.5 (21.36)
Posttest 2	125.25 (10.31)	119.83 (30.22)
Forearm pronation		
Pretest	63.13 (19.14)	67.67 (16.81)
Posttest 1	61.63 (30.42)	64 (27.94)
Posttest 2	65.63 (23.37)	59.17 (18.28)
Forearm supination		
Pretest	38 (29.89)	51.33 (24.87)
Posttest 1	38.13 (29.92)	47.5 (33.58)
Posttest 2	55.13 (27.48)	53.33 (27.14)
Wrist extension		

Pretest	20.25 (17.5)	36.67 (19.41)
Posttest 1	23.13 (19.81)	40.83 (22.71)
Posttest 2	26.25 (21.67)	39.17 (22.23)

Table 5.

Mean and standard deviation (SD) for strength, grip and pinch across pretest, posttest 1, and posttest 2 (N = 14)

Variables	Group A Mean (SD)	Group B Mean (SD)
Shoulder flexion		
Pretest	14.91 (7.01)	14.48 (6.99)
Posttest 1	15.13 (5.30)	18.06 (11.53)
Posttest 2	17.36 (10.08)	21.13 (15.22)
Shoulder abduction		
Pretest	15.10 (6.24)	17.82 (10.69)
Posttest 1	15.32 (6.57)	16.99 (11.73)
Posttest 2	17.65 (9.70)	18.68 (13.61)
Elbow extension		
Pretest	12.90 (5.27)	13.97 (7.77)
Posttest 1	11.98 (3.13)	16.43 (7.81)
Posttest 2	12.81 (6.62)	17.56 (10.46)
Forearm pronation		
Pretest	10.83 (4.99)	11.87 (5.49)
Posttest 1	10.97 (3.60)	11.51 (6.30)
Posttest 2	11.74 (6.29)	11.98 (9.96)
Forearm supination		
Pretest	6.06 (4.86)	7.74 (3.74)
Posttest 1	5.76 (3.56)	6.57 (3.12)
Posttest 2	6.30 (3.36)	8.15 (3.74)
Wrist extension		
Pretest	8.72 (6.13)	11.98 (7.20)
Posttest 1	8.38 (5.76)	15.20 (11.59)
Posttest 2	9.74 (6.17)	14.79 (11.31)
Grip		
Pretest	13.21 (7.06)	29.39 (18.83)
Posttest 1	13.77 (9.62)	28.50 (22.33)
Posttest 2	17.38 (6.79)	28.55 (17.76)
Palmar pinch		
Pretest	.67 (1.28)	6.06 (6.50)
Posttest 1	.88 (1.1)	4.95 (6.71)
Posttest 2	1.17 (1.73)	5.11 (5.78)
Lateral pinch		
Pretest	6.94 (3.71)	17.72 (12.61)
Posttest 1	7.32 (4.82)	16.72 (14.28)
Posttest 2	9.27 (3.53)	16.84 (11.13)

Hypotheses Examination

Research questions were 1) the efficacy of the forearm rotation orthosis when used as sole intervention; 2) the effects of the OTTO intervention both as sole intervention and in combination with the orthosis; and 3) the efficacy of the OTTO intervention in combination with orthosis when compared to OTTO intervention as sole intervention. Inferences were made through examining null hypotheses of these questions with linear mixed effects models.

In each model, the main effects of group and time and the interaction effects between group and time were explored. Since the interaction effects were found not significant in all models, it was removed from all analyses below.

Examination of null hypothesis 1: Participants who use the forearm rotation orthosis as their only intervention will demonstrate no significant difference at posttest 1 for all outcome variables from those who have no intervention, when corrected for pretest score.

The pretest was set as a reference for comparisons. Primary outcome measures were analyzed using Model 1 through 6 (Table 6) and secondary outcome measures used Model 11 through 16 for ROM (Table 8), strength Model 17 through 22 (Table 9), and grip and pinch Model 23 through 25 (Table 10). After correction for multiple analyses the level of significance was set at $p < .017$ for primary outcome measures, $p < .008$ for ROM and strength, and $p < .017$ for grip and pinch.

Controlling for effects of posttest 2, no significant improvements between pretest and posttest 1 as well as between Group A and B were found in primary and secondary outcome measures.

Examination of null hypothesis 2 (functional performance): Participants who receive the OTTO intervention both as the solo intervention and in combination with the orthosis, would demonstrate no significant improvement in functional performance (i.e., the COPM, the MAL and the WMFT) when compared pretest to posttest 2 and posttest 1 to posttest 2.

Six linear mixed effects models were used to analyze differences in functional performance between the time periods (pretest/posttest 1 and posttest 2. *Group* and *time* were entered into all models as the fixed effects and *participant* was entered as the random effect to control for differences in intraclass correlation (ICC) across participants (Table 6; Model 1-6). Significance was set at $p < .017$ because there were three functional outcomes. COPM: Self-perceived overall performance and satisfaction of the two groups across time are illustrated in Figures 4 and 5. WMFT: Changes in performance time and function of the two groups across time are illustrated in Figures 6 and 7. MAL: Changes in self-reported amount of hand use and quality of use of the two groups across time are illustrated in Figures 8 and 9.

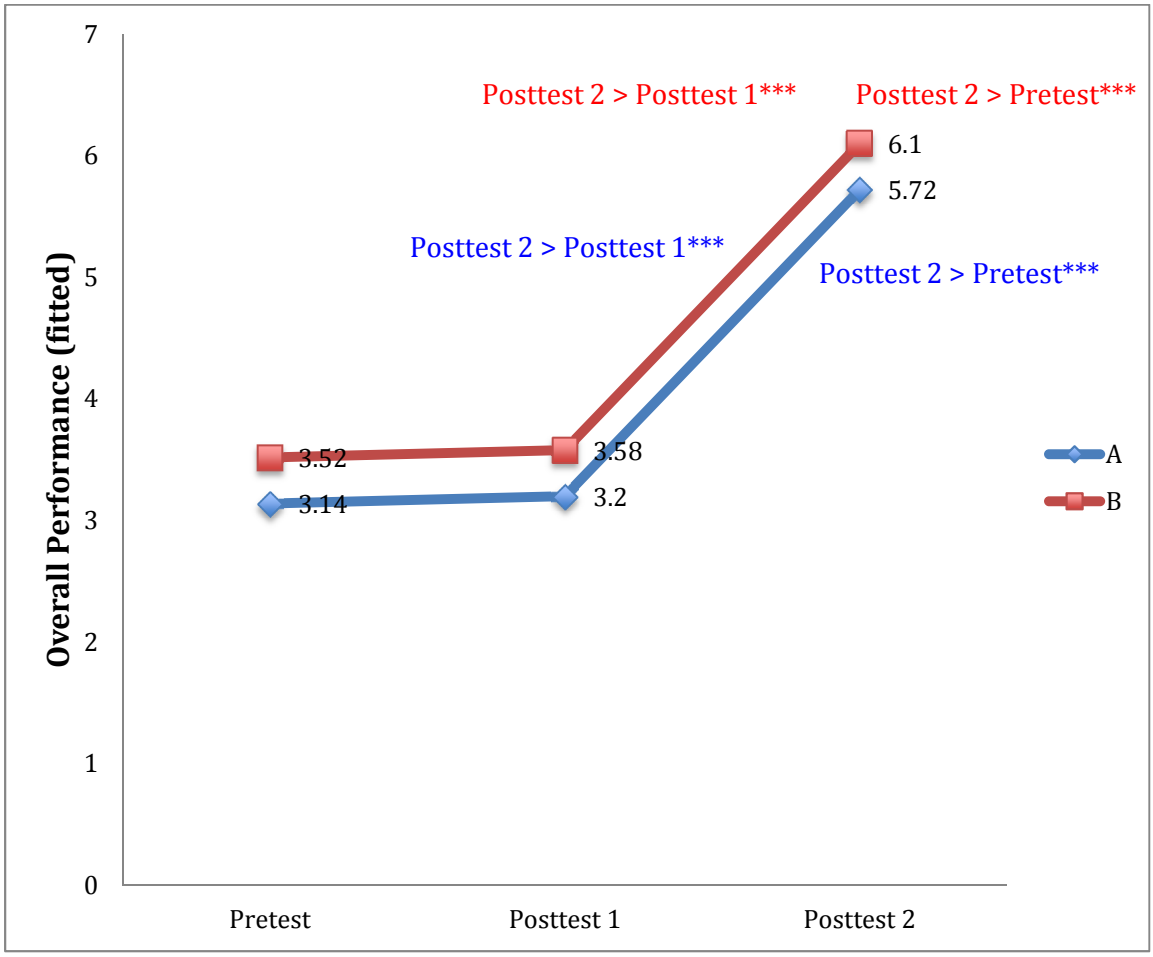

Figure 4. Fitted model value of performance on COPM across time for Group A and B.

***:$p < .00001$

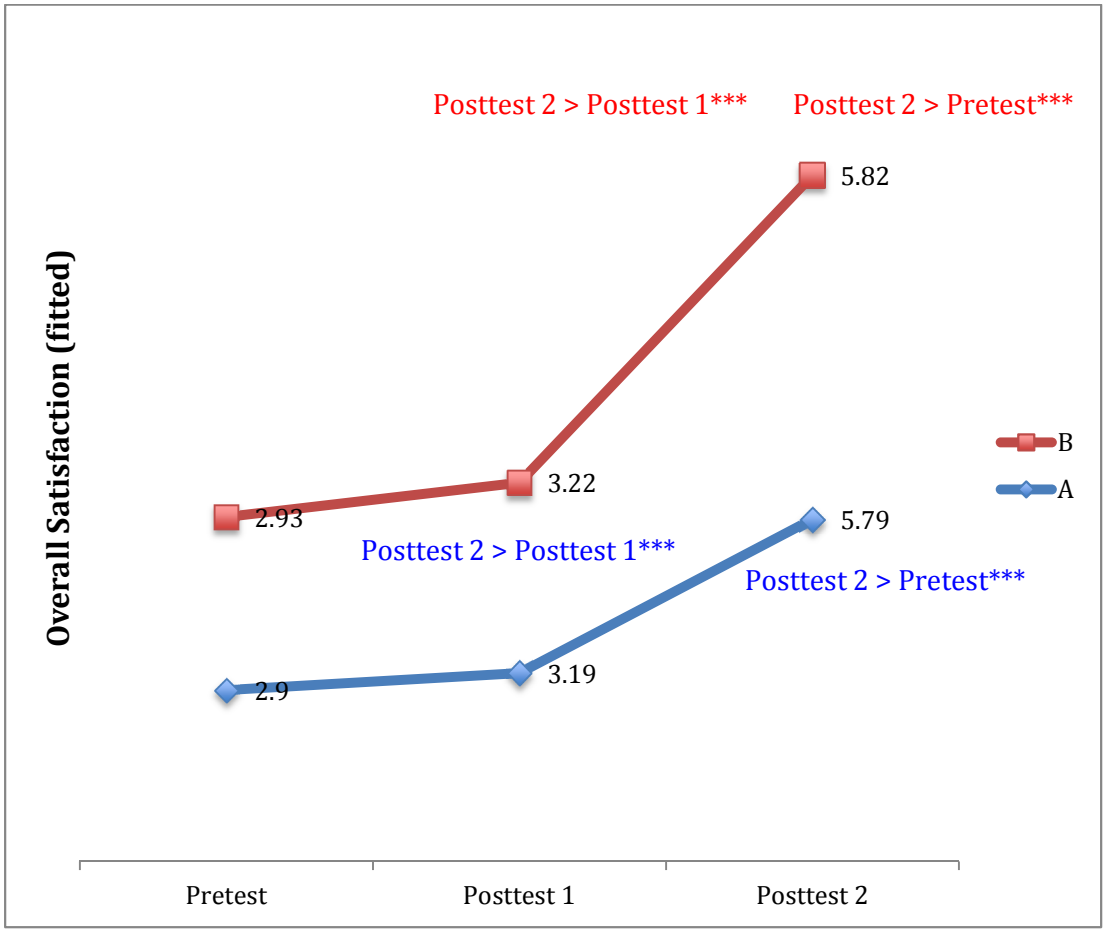

Figure 5. Fitted model value of satisfaction on COPM across time for Group A and B.

***: $p < .00001$

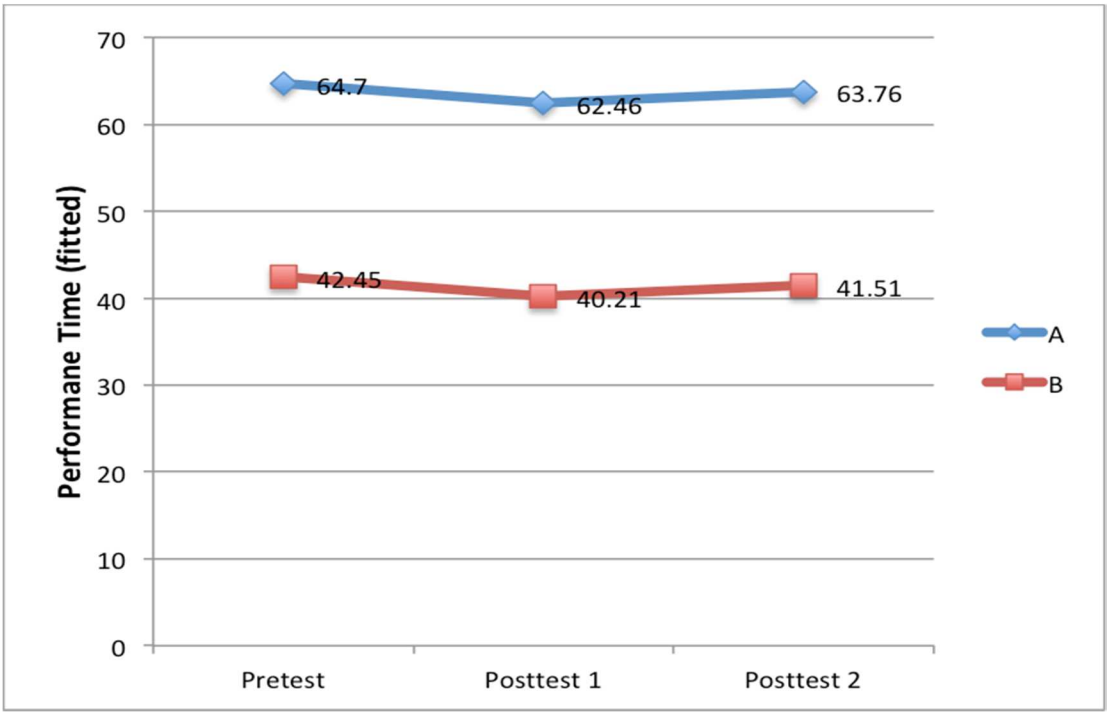

Figure 6. Fitted model value of performance time on the WMFT across time for Group A and B.

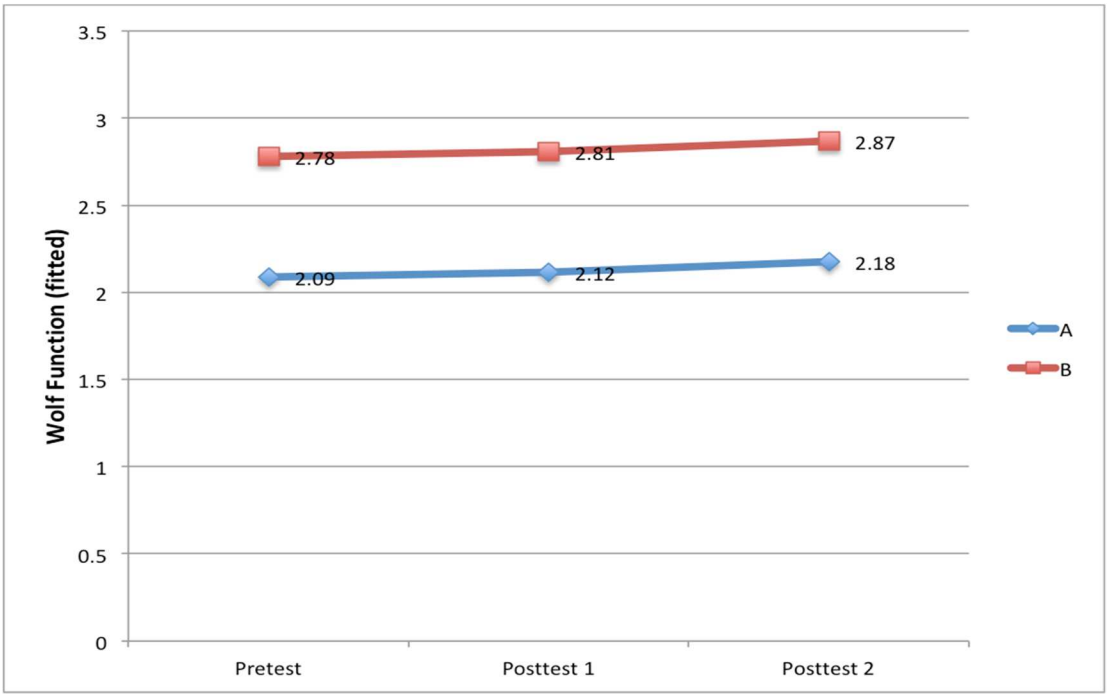

Figure 7. Fitted model value of function on the WMFT across time for Group A and B.

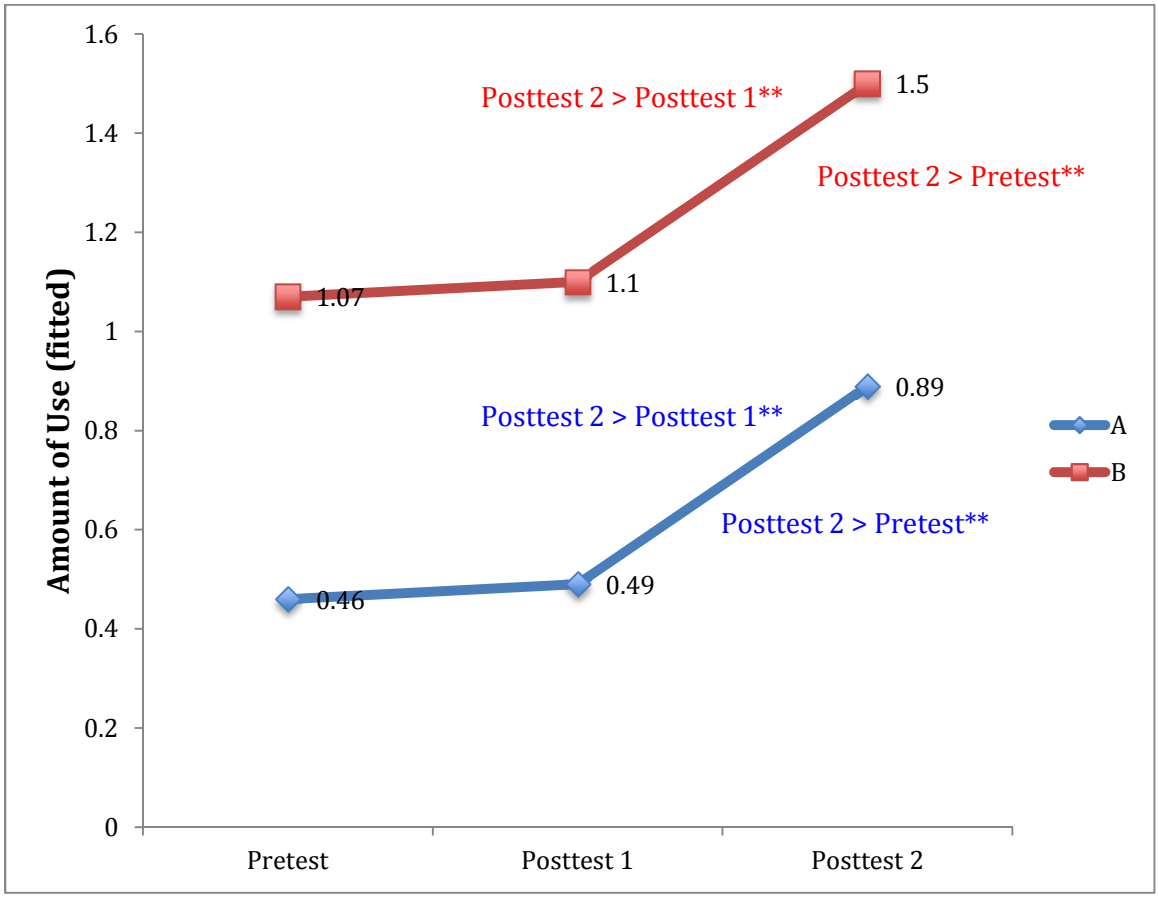

Figure 8. Fitted model value of Amount of Use on MAL across time for Group A and B.

**: $p < .001$

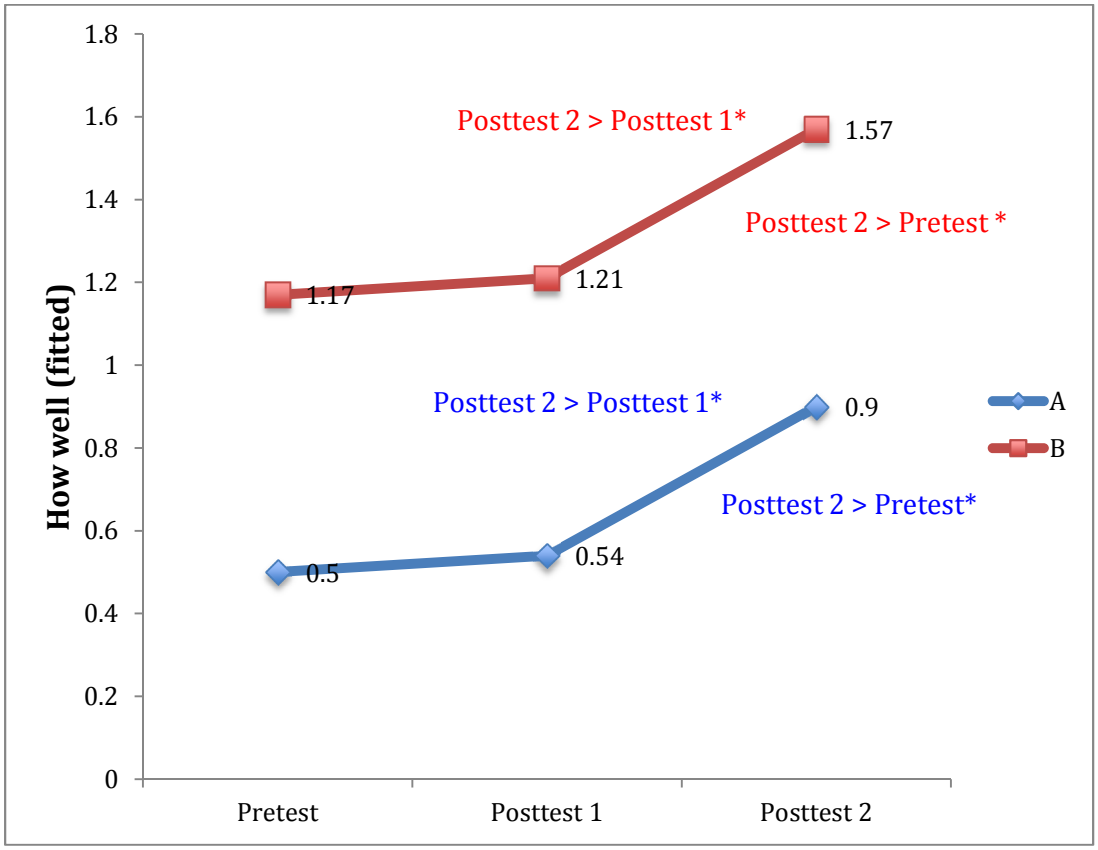

Figure 9. Fitted model value of How Well of use of the affected limb on MAL across time for Group A and B.

*: $p < .017$

Table 6.

Estimates of linear mixed effects models for primary outcome measures across pretest, posttest 1, and posttest 2 (N = 14)

Effect	Model 1: COPM Performance	Model 2: COPM Satisfaction	Model 3: WMFT Time	Model 4: WMFT Function	Model 5: MAL- Amount of Use	Model 6: MAL- How Well
			Fixed effects			
Intercept (Group A/pretest)						
β (SE)	**3.14 (.40) *** **	**2.90 (.44) *** **	**64.70 (10.05) *** **	**2.09 (.29) *** **	.46(.27)	.50 (.28)
Group B						
β (SE)	.38 (.56)	.03 (.63)	-22.25 (15.25)	.69 (.44)	.61 (.40)	.67 (.42)
Posttest 1						
β (SE)	.06 (.29)	.29 (.27)	-2.24 (1.97)	.03 (.09)	.03 (.10)	.04 (.12)
Posttest 2						
β (SE)	**2.58 (.29) *** **	**2.89 (.27) *** **	-.94 (1.97)	.09 (.09)	**.43 (.10) ** **	**.40 (.12) ***
			Random effects			
Participant						
Variance	.87	1.19	788.05	.64	.54	.56
SD	.93	1.09	28.07	.80	.73	.75
Residual						
Variance	.60	.51	27.08	.06	.08	.09
SD	.77	.72	5.20	.24	.27	.31

Note. Variables reached level of significance are in boldface.
*: $p < .017$; **: $p < .001$; ***:$p < .0001$

After controlling for effects of posttest 1, by the end of study (posttest 2) both groups demonstrated significant improvement in COPM self-perceived overall performance (β = 2.58, SE = .29, t = 8.81, ICC = .59, p < .0001) (Table 6; Model 1), COPM self-perceived overall satisfaction (β = 2.89, SE = .27, t = 10.7, ICC = .70, p < .0001) (Table 6; Model 2), MAL self-reported amount of the affected limb use (β = .43, SE = .1, t = 4.17, ICC = .87, p < .001) (Table 6; Model 5), and MAL self-reported quality of use of the affected limb (β = .4, SE = .12, t = 3.45, ICC = .86, p < .017, Table 6; Model 6). Neither Group A nor Group B showed significant change in WMFT performance time (p = .64, Table 3; Model 3) or WMFT function (p= .32, Table 3; Model 4).

To compare posttest 1 to posttest 2, a second linear mixed effect models using posttest 1 as a reference were used (Table 7; Model 7-10). Both groups improved significantly in COPM self-perceived overall performance (β = 2.52, SE = .29, t = 8.61, ICC = .59, p < .0001) (Table 7; Model 7), COPM self-perceived overall satisfaction (β = 2.66, SE = .27, t = 9.85, ICC = .70, p < .0001) (Table 7; Model 8), MAL self-reported amount of use (β = .4, SE = .1, t = 3.88, ICC = .87, p < .001) (Table 7; Model 9), and MAL self-report quality of using the affected limb (β = .36, SE = .12, t = 3.14, ICC = .86, p < .017) (Table 7; Model 10) at posttest 2, when effect of pretest was controlled.

Table 7.

Estimate of second linear mixed effect models for primary outcome variables across pretest, posttest 1, and posttest 2 (N = 14)

Effect	Model 7: COPM Performance	Model 8: COPM Satisfaction	Model 9: MAL- Amount of Use	Model 10: MAL- How Well
		Fixed effects		
Intercept (Group A/posttest 1)				
β (SE)	**3.20 (.40) *** **	**3.13 (.44)*** **	.49 (.27)	.54 (.28)
Group B				
β (SE)	.38 (.56)	.03 (.63)	.61 (.40)	.67 (.42)
Posttest 2				
β (SE)	**2.52 (.29) *** **	**2.66 (.27) *** **	**.40 (.10) ** **	**.36 (.12) * **
Pretest				
β (SE)	-.06 (.29)	-.23 (.27)	-.03 (.10)	-.04 (.12)
		Random effects		
Participant				
Variance	.87	1.19	.54	.56
SD	.93	1.09	.73	.75
Residual				
Variance	.60	.51	.08	.09
SD	.77	.72	.27	.31

Note. Variables reached level of significance are in boldface.
*: $p < .017$; **: $p < .001$; ***: $p < .00001$

Examination of null hypothesis 2 (impairments): There would be no significant difference in secondary outcome measures (i.e., active ROM and strength of UE, grip, palmar pinch, and lateral pinch) following intervention of OTTO alone and in combination with the orthosis**.**

Fifteen linear mixed effects models were performed to examine differences in secondary outcome variables between pretest and posttest 2. *Group* and *time* were entered as the fixed effects and *participant* was entered as the random effect to control for differences in intraclass correlation (ICC). Level of significance was set at .008 for ROM and strength and .017 for grip and pinch. Models for active ROM are listed in

Table 8 (Model 11 through 16), strength listed in Table 9 (Model 17 through 22), and grip and pinch listed in Table 10 (Model 23 through 25).

Participants who received the OTTO intervention alone or in combination with the orthosis showed no significant differences between pretest and posttest 2 in active ROM of UE, strength, grip and pinch (Table 8 through 10) when the effects of posttest 1 was controlled.

Table 8.

Estimates of fixed and random effects models for AROM across pretest, posttest 1, posttest 2 (N = 14)

Effect	Model 11: Shoulder Flexion	Model 12: Shoulder Abduction	Model 13: Elbow Extension	Model 14: Forearm Pronation	Model 15: Forearm Supination	Model 16: Wrist Extension
			Fixed effects			
Intercept (Group A/pretest)						
β (SE)	**102.8 (11.8)****	**95.1 (10.07)****	**114.0 (7.62)****	**65.01 (7.81)****	**40.73 (10.08)***	20.57 (7.16)
Group B						
β (SE)	-2.88 (17.59)	1.28 (14.63)	-5.99 (10.85)	.15 (10.95)	6.97 (15.0)	15.68 (10.76)
Posttest 1						
β (SE)	-8.7 (4.57)	-9.0 (5.37)	2.14 (4.79)	-2.43 (5.39)	-1.57 (3.98)	3.43 (2.18)
Posttest 2						
β (SE)	-3.07 (4.57)	-6.79 (5.37)	11.5 (4.79)	-2.21 (5.39)	10.64 (3.98)	4.5 (2.18)
			Random effects			
Participant						
Variance	1011.4	661.2	350.5	341.1	734.1	385.73
SD	31.8	25.71	18.72	18.47	27.09	19.64
Residual						
Variance	146.4	218.0	160.3	210.3	110.9	33.33
SD	12.1	14.77	12.66	14.5	10.53	5.77

Note. Variables reached level of significance are in boldface.
*: $p < .008$; **: $p < .00001$

Table 9.

Estimates of fixed and random effects models for UE strength across pretest, posttest 1, and posttest 2 (N = 14)

Effect	Model 17: Shoulder Flexion	Model 18: Shoulder Abduction	Model 19: Elbow Extension	Model 20: Forearm Pronation	Model 21: Forearm Supination	Model 22: Wrist Extension
			Fixed effects			
Intercept (Group A/pretest)						
β (SE)	**13.83 (3.26) ****	**15.49 (3.36)****	**11.89 (2.37)****	**11.01 (2.12)****	**6.16 (1.28)****	7.96 (2.74)*
Group B						
β (SE)	2.09 (4.7)	1.81 (4.97)	3.43 (3.45)	.60 (3.10)	1.44 (1.84)	5.05 (3.98)
Posttest 1						
β (SE)	1.66 (1.85)	-.23 (1.43)	.53 (1.24)	-.07 (1.06)	-.67 (.77)	1.18 (1.48)
Posttest 2						
β (SE)	4.25 (1.85)	1.82 (1.43)	1.48 (1.24)	.57 (1.06)	.31 (.77)	1.78 (1.48)
			Random effects			
Participant						
Variance	67.83	79.92	37.24	30.32	10.17	49.17
SD	8.24	8.94	6.10	5.51	3.19	7.01
Residual						
Variance	23.96	14.4	10.83	7.83	4.15	15.36
SD	4.90	3.79	3.29	2.80	2.04	3.92

Note. Variables reached level of significance are in boldface.
*: $p < .008$; **: $p < .001$; ***: $p < .00001$

Table 10.

Estimates of fixed and random effects models for grip, palmar pinch and lateral pinch across pretest, posttest 1, and posttest 2 (N = 14)

Effects	Model 23: Grip	Model 24: Palmar Pinch	Model 25: Lateral Pinch
		Fixed effects	
Intercept (Group A/Pretest)			
β (SE)	**14.13 (4.94) ***	1.06 (1.45)	7.60 (3.09)
Group B			
β (SE)	14.03 (7.44)	4.47 (2.12)	9.25 (4.66)
Posttest 1			
β (SE)	-.06 (1.44)	-.36 (.72)	-.21 (.81)
Posttest 2			
β (SE)	2.02 (1.44)	-.12 (.72)	.95 (.81)
		Random effects	
Participant			
Variance	185.1	14.14	72.85
SD	13.606	3.76	8.54
Residual			
Variance	13.8	3.67	4.63
SD	3.715	1.92	2.15

Note. Variables reached level of significance are in boldface.
*: $p < .008$

Examination of null hypothesis 3: Participants who used the study orthosis in combination with OTTO intervention will have no significant difference in functional performance, active ROM, strength of UE, and grip and pinch at posttest 2 when compared to those who received OTTO intervention only.

Analyses were performed for functional performance (Model 1 through 6; Table 6), active ROM (Model 11 through 16; Table 8), strength of UE (Model 16 through 22; Table 9), and grip and pinch (Model 23 through 25; Table 10). Statistical significance was set at $p < .017$ for functional performance, $p < .008$ for active ROM and UE strength and $p < .017$ for grip and pinch to adjust for multiple planned comparisons. When the effect of time was controlled, no significant differences were found between interventions.

Examination of Adherence to Orthotic Use in Study

Adherence to use of the study orthosis was recorded by the Nike+FuelBand (wristband). The investigator attempted to upload collected data at posttest 1 and posttest 2 from each participant's wristband to cloud storage managed by the Nike Company. Only data from three wristbands was successfully uploaded to the Nike cloud and personnel from Nike customer service informed the investigator that the collected data could be read only if successfully uploaded to that cloud. In addition, the Nike Company indicated that the wristband had become "outdated" during the time since the study's initial effort, and they had no new product to use in its stead. Due to multiple technical issues with the wristband, it was not possible to analyze orthotic adherence.

Participants' Feedback on Satisfaction with the OTTO Intervention

At posttest 2, participants were asked what they did and did not like about the OTTO intervention. Overall, participants liked the OTTO intervention because it was customized to their needs and used functional tasks of interest to them. They expressed that after the OTTO intervention they had the desire to continue using their affected limb, had confidence about their performance, and continued thinking about what they can do at home. They also appreciated that the OTTO intervention enabled them to problem solve within the clinic and their home environment. Participants also indicated study-related issues they did not like, such as long time commitment, short OTTO intervention period, and difficulties in scheduling for intervention sessions. Summary of participants' feedback regarding their satisfaction with the OTTO intervention can be found in Appendix G.

Discussion

Efficacy of the Forearm Rotation Orthosis

Results suggest that participants who received the forearm rotation orthosis as the only intervention did not demonstrate significantly greater improvement at posttest 1 on functional performance and impairment outcomes than those who had no treatment. Thus, hypothesis #1 was supported as expected. There was no evidence of statistically greater improvement in functional performance and impairment outcomes at posttest 2 in participants who received the OTTO intervention in combination with the orthosis compared to those who received the OTTO intervention only. Thus hypothesis #3 was not supported. These results would suggest that the forearm rotation orthosis was not an

effective intervention alone and did not enhance outcomes when combined with the OTTO approach. However, because the study was unsuccessful in monitoring adherence with orthotic use, it is possible the orthosis adherence was not sufficient to provide a beneficial effect. Thus, the efficacy of forearm rotation orthosis for persons with a hemiparetic arm remains unclear.

It was essential to understand participants' use of the affected limb during the day, particularly, with their use of the orthosis. An orthosis-wearing diary was proposed to monitor participants' adherence with orthotic use initially. However, this type of self-report measurement relies on memory recall and has raised concerns of accuracy that poor adherence tends to be underreported and good adherence tends to be overly reported (Dunbar, Dunning, & Dwyer, 1989). To avoid this, it was decided to pursue a portable device that provides objective data. At the time, the Nike+FuelBand was the most advanced portable wristband on the market that used three accelerometers to measure 3-dimensional movements of the involved limb. One limitation of the wristband is that users need to manually connect the wristband with a computer to upload data to cloud storage managed by the Nike Company. Even so, this was considered a better way of monitoring orthotic adherence to replace the orthosis-wearing diary. However, due to technical failure of the wristband, data could not be uploaded at scheduled collection times in most participants. This has made analysis of orthotic adherence impossible. As a result we don't know whether the forearm rotation orthosis was not effective or participants did not wear it with sufficient intensity for it to be effective.

The efficacy of the forearm rotation orthosis could be washed out because of the study's broad inclusion criteria. One of the criteria required participants to have at least 10 degrees of shoulder flexion, abduction, and elbow flexion. This allowed persons post-stroke with various levels of severity in motor function to be included in the study. This has provided opportunity for examining the effects of OTTO intervention to a broader stroke population. However, the relatively less homogenous sample in the study may have weakened the ability to distinguish participants who may benefit from the orthosis from those who may not. For example, large variation observed in performance time and functionality on the WMFT and impairment measures in both groups suggests that there are various levels of severity in motor function among the study participants. As a result, forearm rotation movements were not the identified critical parameter for all participants who received the orthotic intervention. Likewise, several participants who received the OTTO intervention only were considered good candidates who may have benefitted from the orthosis. In participants who were identified as having forearm rotation movements as the critical control parameter, it seemed that they had at least 15 degrees of active forearm supination at the pretest. The orthosis would likely not be beneficial if participants did not have any AROM at pretest or already had full active forearm supination at the pretest. When participants with forearm rotation movement as the critical control parameter are combined with others for whom it was not a critical control parameter, the beneficial effects of the orthosis may have been lost.

An orthosis can be beneficial for persons post-stroke during functional tasks when used in combination with functional training (i.e., the OTTO intervention). It appeared

that the forearm rotation orthosis used in the study was beneficial in several participants when active forearm rotation movements were identified as the critical parameter during the orthosis combined with OTTO intervention phase. With assistance in supination/pronation from the orthosis, participants were able to resume their previous valued tasks or showed improved functional use of the affected limb. For example, a participant could rotate the forearm to play the piano with both hands for 15 minutes; a participant was able to hold her affected forearm in slight supination doing crocheting for 10 minutes; a participant was able to rotate the affected forearm and pull out a credit card from the front pocket when stopped at a parking ramp; a participant was able to hold the affected forearm in slight supination for holding a stylus pen to type on keyboard for his resume or to use social media on an iPad; or a participant used the orthosis to assist forearm supination during feeding tasks. These examples suggest that combined with the OTTO intervention, the forearm rotation orthosis could be used to assist anti-gravity forearm rotation during valued tasks. Regretfully, further analysis regarding the efficacy of the orthosis could not be done without evidence of adherence to orthotic use.

Effects of the OTTO Intervention

The results of analyses on functional performance and impairment outcomes suggest that there was evidence of statistically greater improvements in self-perceived functional performance in participants who received the OTTO intervention both as the sole intervention and in combination of use of the orthosis. Following the OTTO intervention participants reported significant improvements in self-perceived overall performance and satisfaction on the COPM as well as self-perceived rating of amount and quality use of

the affected limb on the MAL. However, changes in functional use of the affected limb measured by the WMFT were not statistically significant. No significant increase in active ROM and strength of UE, grip, and pinch were found in participants who received the OTTO intervention. The findings from this study are similar to those reported by Almhdawi et al. (2016) that the OTTO intervention may benefit persons post-stroke on the activity participation level, but not on the impairment level. The OTTO approach does not focus on the impairment level unless it is considered a critical control parameter for functional performance (Almhdawi et al., 2016). Thus, it is likely that the intensity of interventions to improve AROM and strength of the UE were not sufficient to cause significant change in these variables.

Findings of improvement in functional performance from this study may reflect the nature of the OTTO approach for persons post-stroke. Using the OTTO approach, therapists endeavor to improve the person's functional performance (Mathiowetz, 2016). This requires the therapists to identify the critical parameter(s) responsible for improving functional performance (Almhdawi et al., 2016; Mathiowetz, 2016). Depending on the exhibiting performance pattern(s), therapists can apply remedial strategies on the identified parameter(s) to change the pattern(s) when it is determined in-transition and/or compensatory strategies for task completion when the pattern(s) is fixed (Almhdawi et al., 2016; Mathiowetz, 2016). This approach urges the therapists to partner with their clients and genuinely put more weight on improving functional performance, facilitating problem solving capabilities, and generally less emphasis on impairment training (Almhdawi et al., 2016; Mathiowetz, 2016). In addition, the compensatory component of

the OTTO intervention would effect small improvement at the impairment level (Almhdawi et al., 2016). Subsequently, one can expect that participants who received the OTTO intervention would demonstrate greater improvement in functional performance and perhaps less in impairments. Arguably, this is more clinically relevant, more meaningful to participants, and represents more optimal results of rehabilitation services.

Emphasis of OTTO intervention was put on developing participants' ability to problem solve barriers interfering with their functional use of the affected limb. Actual treatment planning was based on the clients' improvement during the treatment period (Flinn, 1995). Flinn (1995) suggested that, since the critical control parameter may change over time, treatment plan should be re-evaluated and/or revised at each session to ensure it reflects the hypothesized parameter. For example, active shoulder movement was identified as the critical parameter for a participant who received the OTTO intervention in combination with the orthosis at week 1. As the performance pattern at the shoulder was thought to be responsive to change, remedial strategies were applied to enhance functional performance as well as shoulder active ROM and strength. The forearm rotation orthosis then functioned as the environmental adaptation for performance during this period (i.e., positioned the forearm in slight supination during feeding or pronation while using computer/mouse). At week 5, active forearm rotation movement was determined as the critical control parameter. Functional and impairment training on functional tasks requiring active forearm rotation movement was emphasized during the last week of OTTO intervention. Continuously examining the hypothesized parameter throughout the treatment period helps the therapists to provide effective and

efficient intervention for the participants. However, one disadvantage was that the participant had significant improvement in functional performance rather than at the impairment level.

A difference in the delivery of the OTTO intervention between current study and Almhdawi et al. (2016) was the intensity of the home exercise program. Almhdawi et al. used a logbook to track in-clinic training and home-based activities for each participant. They used the logbook to ensure the assigned activities offered the 'just-right' challenge and to enhance adherence to therapy. This study, however, employed concepts of self-controlled learning rather than a logbook. Study therapist video recorded participants' performance at each session. Each video clip was reviewed and discussed between therapist and participant right after to facilitate better task performance. Participants were encouraged to apply learned strategies or techniques at home. Self-controlled learning strategies were valuable for motor acquisition and retention (Ste-Marie, Vertes, Law, & Rymal, 2013) and can enhance adherence to therapy (Radomski, 2011). There was evidence that the beneficial effects of OTTO lasted beyond the end of the study. When asked to provide feedback on the OTTO approach at the end of the study, several participants reported enhanced self-efficacy by expressing "I can keep thinking about what I can do at home", "you gave me hope; gave me confidence" or "I will continue to use my arm". Furthermore, one participant contacted the investigator about achieving one of his COPM goals of passing his driver's license test three week post-intervention. Another participant indicated that although he was only able to use his affected limb in

feeding tasks by the end of his participation. He has since started using the affected limb to do woodwork and minor modification for his house.

Comparing the effects of the OTTO approach on functional performance (i.e., COPM) from this study to those from CIMT/mCIT studies (Table 11) can be challenging because of differences in the participants' baseline abilities, the focus of intervention, and intensity of training. Overall, studies following standard CIMT training protocol appeared to have non-significant results on the COPM (Flinn, Schamburg, Fetrow, & Flanigan, 2005). In contrast, studies that used the COPM for task selection and intervention focus tended to have significant improvements in performance and satisfaction in COPM (Gillick et al., 2014; McCall, McEwen, Colantonio, Streiner, & Dawson, 2011; Reidy et al., 2012; Stevenson & Thalman, 2007). Compared to the current study, Reidy et al. (2012) and Stevenson and Thalman (2007) reported better results on the COPM. However, the intensity of their training protocol was greater than our study. Interestingly, the rationale used by Stevenson and Thalman for task selection was very compatible with the concepts of OTTO approach. Based on these studies, it is legitimate to conclude that participants benefited from training protocols that were client-centered and used functional tasks of value to participants during the interventions.

Table 11.

Comparison among CIMT, mCIT, and OTTO studies that used the COPM as outcome measure.

Comparison	CIMT (Flinn et al., 2005)	CIMT (Gillick et al., 2014)	mCIT (McCall et al., 2011)	mCIT (Reidy et al., 2012)	mCIT (Stevenson & Thalam, 2007)	OTTO study
Participants	Adults with chronic stroke (N=11)	Children with congenital hemiparesis (8-17 years old) (N=19)	Adults with acute or sub-acute stroke (N=4)	Children with hemiplegic cerebral palsy or acquired hemiplegia (1.6-19.1 years old) (N=29)	Adults with stroke (N=12)	Adults with chronic stroke (N=14)
Clinical treatment intensity (Total hours of treatment)	3.5 hours/8 days (28 hours)	5 treatments of real/sham rTMS and 5 treatments of CIMT (2 hours) on alternate weekdays for 2 weeks (10 hours + rTMS)	2 hours/5days for 2 weeks (20 hours)	3 (N=17) or 6 (N=12) hours for 21 days (weekdays) (unilateral + bimanual training) (63 or126 hours across groups)	4 hours/5days for 2 weeks (40 hours)	3 hours/week for 6 weeks (18 hours)
Task selection	Based on	Treatment	Specific task	Task selection	Based on	Based on

and treatment	videos from pretest of the Wolf Motor Function Test. Standard CIMT shaping and task practice activity	sessions guided by the COPM. Shaping, repetitive practice of functional tasks, ROM, strengthening	selection based on the COPM Task analysis performed to address participants' motor ability Primarily shaping and repetitive practice of functional task.	based on COPM and activity preference. Shaping and repetitive practice of tasks.	COPM, 1) modify task to be challenging but achievable; 2) feedback to promote participants' learning and motivation; 3) "homework" Each session, practice goals/tasks identified in the COPM for one hour.	COPM, Role checklist, and Interest checklist. Tasks valuable to participants, to 1) modify task for just-right challenge; 2) modify task environment to promote task performance; 3) self-control learning
Post-intervention changes on COPM						
	No significant differences in performance and satisfaction between pretest and	Significant improvements in performance (2.8- treatment & 2.9- control) and satisfaction (2.7 & 2.7,	The trend line analysis was used. Three out of 4 showed significant	Significant improvement in performance (2.8) and satisfaction (5.3) immediately	Significant improvements in performance (3.4) and satisfaction (3.91)	Significant improvements in performance (2.58) and satisfaction (2.89) immediately

	posttest and between pretest and 4-6 month post-intervention.	respectively) found within-groups, but not between-groups.	improvement in performance (.75-1.91) and satisfaction (.17-1.96) after intervention.	after intervention.	immediately after intervention. Improvements maintained 6 months post-intervention.	after intervention.

Note. CIMT = Constraint Induced Movement Therapy; COPM = Canadian Occupational Performance Measure; mCIT = modified Constraint Induced Therapy; rTMS = repetitive transcranial magnetic stimulation.

Responsiveness of Outcome Measures Used in the Study

Measuring instruments used in a clinical trial should not only be able to detect true changes of targeted behavior, but also be sufficiently responsive to detect clinically important difference (Lin et al., 2009; van der Lee et al., 2004). Changes of 2 or more points in performance and satisfaction on the COPM were considered clinically important for persons with a variety of disabilities and across all developmental stages (Law et al., 2005). For persons who have stroke for more than 6 months with spasticity scored less than 2.5 in the Modified Ashworth Scale, the mean change scores on the performance time and function on the WMFT should achieve at least 4.36 seconds and 0.37 points, respectively, to be considered clinically true change (Lin et al., 2009). However, although changes on MAL must be greater than 12-15% of the range of the scale to detect an individual change in persons who have stroke for at least one year, van der Lee et al. (2004) questioned the appropriateness of using the MAL as the primary outcome measure due to its poor longitudinal construct validity.

Results from current study suggest that following the OTTO intervention changes in participants' self-perceived performance and satisfaction on COPM are clinically meaningful. Study participants reported statistically increased use and quality of use of the affected limb in the real world. However, the changes were not clinically important according to van der Lee et al. (2004). In addition, no clinically important changes in UE motor function were found on the WMFT and all impairment measures.

Clinical Implications

This study suggested that the OTTO intervention is beneficial for persons post-stroke in achieving clinically meaningful improvement of performance and satisfaction on the COPM. Elements of the OTTO allows therapists to provide effective and efficient intervention for persons post-stroke, including identification of critical control parameter, use of functional tasks that are of value to the person, repetitive practice of the selected tasks, and facilitation of self-controlled learning. Moreover, a greater emphasis on problem solving should be included in the home exercise program to enhance self-controlled learning and retention of therapeutic effects.

Study findings assist in the refinement of the general guidelines of the OTTO for persons with chronic stroke. Findings from this study confirmed the assumption that the critical control parameter may change over time. It is essential that therapists frequently re-evaluate the client's improvement over time to ensure treatment plan reflect the current control parameter. Visual feedback should be used to enhance self-controlled learning and adherence with intervention.

Study Limitations

The study failed to examine the efficacy of the forearm rotation orthosis for persons post-stroke due to technical failure of the Nike+FuelBand. There was an unexpected 2 years gap between purchase of the wristbands and the first enrolled participant. Not only did the wristband become outdated, its life for usage was shortened. To objectively obtain adherence data, a portable device equipped with multiple accelerometers that can be attached to the orthosis without affecting its effectiveness and can automatically and

periodically upload data to cloud would be ideal. Most importantly, orthosis wearing diary should not be abandoned in case the portable device fails again.

The study only examined the immediate effects of the OTTO intervention as the sole intervention and in combination with the orthosis. Retention of the therapeutic effect of the OTTO intervention is unknown. However, given the design of the study, adding a six-week follow-up session to the design would have increased the length of the study and likely the attrition rate. Furthermore, data from the COPM could be biased because the investigator/interventionist collected it. However, the investigator/interventionist needed to do so in order to better understand the participants and to customize treatment plan.

Sample size was small (N=14) due to limited financial resources and time and this limited the statistical power of the study. A larger sample size could have provided stronger statistical power to strengthen study findings. In addition, a more homogeneous sample targeted to participants who could benefit from a forearm rotation orthosis would have enhanced the likelihood of positive intervention effects.

Future Directions

Future studies examining the effects or efficacy of an orthosis in combination with the OTTO intervention should include a robust plan for monitoring adherence with orthotic use with a larger and more homogeneous sample. Both objective (i.e., a portable tracking device that automatically uploads data to cloud) and self-reported measurements (i.e., an orthosis-wearing diary) should be included for examination of adherence with orthotic use. A larger homogeneous sample would not only improve statistical power to

detect true outcome changes for orthotic intervention, but also help to distinguish persons post-stroke who may benefit from the orthosis from those who may not.

Practice guidelines for the OTTO approach can be refined through examining persons post-stroke with a variety of impairment challenges. It is essential to understand the effects of current guidelines on persons post-stroke with cognitive challenges and/or psychological challenges. It is also important to understand whether the therapeutic effects are maintained over time. Since the OTTO intervention suggests use of body-weight support device/orthoses to assist in anti-gravity movements, studies are needed to compare OTTO approach with and without these devices/orthoses.

Conclusion

This study employed a matched, randomized, two-group, single-blinded, repeated measures design to examine the efficacy of a forearm rotation orthosis when applied as the sole intervention and in combination with the OTTO intervention on functional performance for 14 persons post-stroke. Study results suggest that the 6 weeks of functional training protocol provides clinically important benefits to persons post-stroke in self-perceived functional performance (COPM), but not in motor function (WMFT) and impairment measures (active ROM and strength of UE, grip, and pinch). However, due to technical failure for monitoring adherence of orthotic use, the efficacy of the forearm rotation orthosis for persons post-stroke remains unclear. Studies with a more robust plan for adherence with orthotic use, post-intervention follow-ups, and a larger, more homogeneous sample need to be conducted. Studies examining the effects of OTTO

intervention for persons post-stroke with cognitive or psychological challenges should also be conducted.

References

Ada, L., Dorsch, S., & Canning, C. G. (2006). Strengthening interventions increase strength and improve activity after stroke: a systematic review. *Australian Journal of Physiotherapy, 52*, 241-248.

Ada, L., O'Dwyer, N., & O'Neill, E. (2006). Relationship between spasticity, weakness and contracture of the elbow flexors and upper limb activity after stroke: An observation study. *Disability and Rehabilitation, 28*, 891-897. Doi: 10.1080/09638280500535165

Almhdawi, k. (2011). *Effect of occupational therapy task-oriented approach in upper extremity post-stroke rehabilitation.* (doctoral dissertation). University of Minnesota, MN, USA. Retrieved from http://search.proquest.com.ezp1.lib.umn.edu/docview/898767734?accountid=14586

Almhadwi, K., Mathiowetz, V. G., White, M., & delMas, R. C. (2016). Efficacy of occupational therapy task-oriented approach in upper extremity post-stroke rehabilitation. *Occupational Therapy International, 23*, 444-456. Doi: 10.1002/oti.1447

Basaran, A., Emre, U., Karadavut, K. I., Balbaloglu, O., & Bulmus, N. (2012). Hand splinting for poststroke spasticity: A randomized controlled trial. *Topics in Stroke Rehabilitation, 19(4)*, 329-337. Doi: 10.1310/tsr1904-329.

Bates, D., Maechler, M., & Bolker, B. (2012). Lme4: Linear mixed-effects models using S4 classes R package version 0.999999-0. Retrievd from http://CRAN.R-project.org/package=lme4

Bayona, N. A., Bitensky, J., Salter, K., & Teasell, R. (2005). The role of task-specific training in rehabilitation therapies. *Top Stroke Rehabilitation, 12*, 58-65.

Beer, R. F., Dewald, J. P. A., & Rymer, W. Z. (2000). Deficits in the coordination of multijoint arm movements in patients with hemiparesis: Evidence for disturbed control of limb dynamics. *Experiment Brain Research, 131*, 305-319. Doi: 10.1007/s002219900275

Bienenstock, E. L., Copper, L. N., & Munro, P. W. (1982). Theory for the development of neuron selectivity: Orientation specificity and binocular interaction in visual cortex. *Journal of Neuroscience, 2*, 32-48.

Bhakta, B. B. (2000). Management of spasticity in stroke. *British Medical Bulletin, 56*(2), 476-485.

Bobath, B. (1948). The importance of the reduction of muscle tone and the control of mass reflex action in the treatment of spasticity. *Occupational Therapy Rehabilitation, 27*(5), 371-383.

Bohannon, R. W. (1998). Hand-grip dynamometry provides a valid indication of upper extremity

strength impairment in home care patients. *Journal of Hand Therapy, 11*, 258-260. Doi:

10.1016/S0894-1130(98)80021-5

Bowman, A. W. & Azzalini, A. (2014). R package 'sm': Nonparametric smoothing methods (version 2.2-5.4) URL http://www.stats.gla.ac.uk/~adrian/sm, http://azzalini.stat.unipd.it/Book_sm.

Braendvik, S. M., Elvrum, A. G., Vereijken, B., & Roeleveld, K. (2010). Relationship between neuromuscular body functions and upper extremity activity in children with cerebral palsy. *Developmental Medicine & Child Neurology, 52*, e29-e34. Doi:10.1111/j.1469-8749.2009.03490.x

Burtner, P. A., Poole, J. L., Medora, A. M., Abeyta, R., Keene, J., & Qualls, C. (2008). Effect of wrist hand splints on grip, pinch, manual dexterity, and muscle activation in children with spastic hemiplegia: A preliminary study. *Journal of Hand Therapy, 21*, 36-43.

Butler, E. E., Ladd, A. L., Louie, S. A., & LaMont, L. E. (2010). Three-dimensional kinematics of the upper limb during a reach and grasp cycle for children. *Gait & Posture, 32*, 72-77. Doi:10.1016/j.gaitpost.2010.03.011

Cassidy, J. M., Gillick, B. T., & Carey, J. R. (2014). Priming the brain to capitalize on metaplasticity in stroke rehabilitation. *Physical Therapy, 94*, 139-150. Doi: 10.2522/ptj.20130027

Coppard, B. M. (2008). Foundations of splinting. In B. M. Coppard, & H. Lohman (Eds.), *Introduction to splinting: A clinical reasoning and problem-solving approach* (3rd ed., pp. 3-14). St. Louis: Mosby.

Crum, R. M., Anthony, J. C., Bassett, S. S., & Folstein, M. F. (1993). Population-based norms for the mini-mental state examination by age and educational level. *Journal of the American Medical Association, 269*, 2386-2391.

Cup, E., Reimer, W. S. O., Thijssen, M., & van Kuyk-Minis, M. (2003). Reliability and validity of the Canadian occupational performance measure in stroke patients. *Clinical Rehabilitation, 17*, 402-409.

Dickstein, R., Hocherman, S., Pillar, T., & Shaham, R. (1986). Stroke rehabilitation: Three exercise therapy approaches. *Physical Therapy, 66*, 1233-1238. Doi: 10.1093/ptj/66.8.1233

Donohue, M. C., & Edland, S. D. (2016). Longpower: Power and sample size calculators for longitudinal data. R package version 1.0-16

Dunbar, J., Dunning, E. J., & Dwyer, K. (1989). Compliance measurement with arthritis regimen. *Arthritis Care and Research, 2*, s8-s16.

Duncan, P. W., Goldstein, L. B., Horner, R. D., Landsman, P. B., Samsa, G. P., & Matchar, D. B. (1994). Similar motor recovery of upper and lower extremities after stroke. *Stroke, 25*, 1181-1188. Doi:10.1161/01.STR.25.6.1181

Dunning, K., Berberich, A., Albers, B., Mortellite, K., Levine, P. G., Hermann, V. A. H., & Page, S. J. (2008). A four-week, task-specific neuroprosthesis program for a person with no active wrist or finger movement because of chronic stroke. *Physical Therapy, 88*, 397-405. Doi:10.2522/ptj.20070087

Duque, J., Hummel, F., Celnik, P., Murase, N., Mazzocchio, R., & Cohen, L. G. (2005). Transcallosal inhibition in chronic subcortical stroke. *NeuroImage, 28*, 940-946. Doi: 10.1016/j.neuroimage.2005.06.033

Farrel, J. F., Hoffman, H. B., Snyder, J. L., Giuliani, C. A., & Bohannon, R. W. (2007). Orthotic aided training of the paretic upper limb in chronic stroke: Results of a phase 1 trial. *NeuroRehabilitation, 22*, 99-103.

Fellows, S. J., Kaus, C., & Thilmann, A. F. (1994). Voluntary movement at the elbow in spastic hemiparesis. *Annals of Neurology, 36*, 397-407.

Fess, E. W. (2002). A history of splinting: To understand the present, view the past. *Journal of Hand Therapy, 15*, 97-132.

Flinn, N. (1995). A task-oriented approach to the treatment of a client with hemiplegia. *American Journal of Occupational Therapy, 49*(6), 560-569.

Flinn, N. A., Schamburg, S., Fetrow, J. M., & Flanigan, J. (2005). The effects of constraint induced movement treatment on occupational performance and satisfaction in stroke survivors. *Occupational Therapy Journal of Research: Occupation, Participation and Health, 25*, 119-127.

Francis, H. P., Wade, D. T., Turner-Stokes, L., Kingswell, R. S., Dott, C. S., & Coxon, E. A. (2004). Does reducing spasticity translate into functional benefit? An exploratory meta-analysis. *Journal of Neurology, Neurosurgery and Psychiatry, 75*, 1547-1551.

Fritz, S. L., Light, K. E., Patterson, T. S., Behrman, A. L., & Davis, S. B. (2005). Active finger extension predicts outcomes after constraint-induced movement therapy for in individuals with hemiparesis after stroke. *Stroke, 36*, 1172-1177. Doi: 10.1161/01.STR.0000165922.96430.d0

Fu, T. S. -., Wu, C. Y., Lin, K. C., Hsieh, C. J., Liu, J. S., Wang, T. N., & Ou-yang, P. (2011). Psychometric comparison of the shorten Fugl-Meyer assessment and the streamlined Wolf motor function test in stroke rehabilitation. *Clinical Rehabilitation, 26*(11), 1043-1047. Doi: 10.1177/0269215511431474

Gillen, G. (2000). Improving activities of daily living performance in an adult with ataxia. *American Journal of Occupational Therapy, 54*(1), 89-96.

Gillen, G. (2002). Improving mobility and community access in an adult with ataxia. *American Journal of Occupational Therapy, 56*(4), 462-466.

Gillen, G. & Nilsen, D. M. (2015). Upper extremity function and management. In G. Gillen (Ed.), *Stroke rehabilitation: A function-based approach* (4th ed., pp. 424-485). St. Louis: Mosby.

Gillen, G. (2016). Orthotic devices after stroke. In G. Gillen (Ed.), *Stroke rehabilitation: A function-based approach* (4th ed., pp. 529-552). St. Louis: Mosby.

Gillick, B. T., Krach, L., Feyma, T., Rich, T. L., Moberg, K., Thomas, W., Cassiday, J. M., Menk, J., & Carey, J. R. (2014). Primed low-frequency repetitive transcranial magnetic stimulation and constraint-induced movement therapy in pediatric hemiparesis: A randomized controlled trial. *Developmental Medicine and Child Neurology, 56*, 44-52. Doi: 10.1111/dmcn.12243.

Gueorguieva, R., & Krystal, J. H. (2004). More over ANOVA: Progress in analyzing repeated-measures data and its reflection in papers published in the Archives of General Psychiatry. *Archives of General Psychiatry, 61*, 310-317.

Hardy, K., Suever, K., Sprague, A., Hermann, V., Levine, P., & Page, S. J. (2010). Combined bracing, electrical stimulation, and functional practice for chronic, upper-extremity spasticity. *American Journal of Occupational Therapy, 64*, 720-726.

Harris-Love, M., Perez, M. A., Chen, R., & Cohen, L. G. (2007). Interhemispheric inhibition in distal and proximal arm representations in the primary motor cortex. *Journal of Neurophysiology, 97*, 2511-2515. Doi: 10.1152/jn.01221.2006

Hinder, M. R., Schmidt, M. W., Garry, M. I., & Summers, J. J. (2010). Unilateral contractions modulate interhemispheric inhibition most strongly and most adaptively in the homologous muscle of the contralateral limb. *Experiment Brain Research, 205*, 423-433. Doi: 10.1007/s00221-010-2379-z

Hoffman, H. B., & Blackey, G. L. (2011). New design of dynamic orthoses for neurological conditions. *NeuroRehabilitation, 28*, 55-61. Doi:10.3233/NRE-2011-0632

Howle, J. M. (Ed.). (2002). Neuro-developmental treatment approach: Theoretical foundations and principles of clinical practice. Laguna Beach: Neuro-Developmental Treatment Association.

Hsieh, Y. -., Hsueh, I. -., Chou, Y. -., Sheu, C. -., Hsieh, C. -., & Kwakkel, G. (2007). Development and validation of a short form of the Fugl-Meyer motor scale for patients with stroke. *Stroke, 38*, 3052-3054. Doi:10.1161/STROKEAHA.107.490730

Jung, Y. J., Hong, J. H., Kwon, H. G., Song, J. C., Kim, C., Park, S., Kim, Y. K….J. S. H. (2011). The effect of a stretching device on hand spasticity in chronic hemiparetic stroke patients. *NeuroRehabilitation, 29*, 53-59. Doi: 10.3233/NRE-2011-0677.

Kinghorn, J., & Roberts, G. (1996). The effect of an inhibitive weight-bearing splint on tome and function: A single-case study. *American Journal of Occupational Therapy, 50*(10), 807815.

Kollen, B. J., Lennon, S., Lyons, B., Wheatley-Smith, L., Scheper, M., Buurke, J. H., Halfens, J., Geuts, A. C. H., & Kwakkel, G. (2009). The effectiveness of Bobath concept in stroke rehabilitation: What is the evidence? *Stroke, 40*, e89-e97. Doi: 10.1161/STROKEAHA.108.533828

Koyama, T., Sano, K. Tanaka, S., Hatanaka, T., & Domen, K. (2007). Effective targets for constraint-induced movement therapy for patients with upper-extremity impairment after stroke. *NeuroRehabilitation, 22*, 287-293.

Kuznetsova, A., Brockhoff, P. B. & Christensen, R. H. B. (2017). ImerTest package: Tests in linear mixed effects models. *Journal of Statistical Software, 82*, 1-26. Doi: 10.18637/jss.v082.i13

Lai, J. M., Francisco, G. E., & Willis, F. B. (2009). Dynamic splinting after treatment with Botulinum toxin type-A: A randomized controlled pilot study. *Advance Therapy, 26*, 241-248. Doi: 10.1007/s12325-008-0139-2

Lambercy, O., Dovat, L., Yun, H., Wee, S. K., Kuah, C. WK., Chua, K. SG., Gassert, R.…& Burdet, E. (2011). Effects of a robot-assisted training of grasp and pronation/supination in chronic stroke: A pilot study. *Journal of NeuroEngineering and Rehabilitation, 8*:63

Lannin, N. A. & Ada, L. (2011). Neurorehabilitation splinting: Theory and principles of clinical use. *NeuroRehabilitation, 28*, 21-28. Doi:10.3233/NRE-2011-0628

Lannin, N. A., Cusick, A., McCluskey, A., & Herbert, R. (2007). Effects of splinting on wrist contracture after stroke: A randomized controlled trial. *Stroke, 38*, 111-116.

Lannin, N. A., & Herbert, R. (2003). Is hand splinting effective for adults following stroke? A systematic review and methodological critique of published research. *Clinical Rehabilitation, 17*, 807-816.

Lannin, N. A., Horsley, S. A., Herbert, R., McCluskey, A., & Cusick, A. (2003). Splinting the hand in the functional position after brain impairment: A randomized controlled trial. *Archives Physical Medicine and Rehabilitation, 84*, 297-302.

Law, M., Baptiste, S., Carswell, A., McColl, M. A., Polatajko, H., & Pollock, N. (2005). Canadian Occupational Performance Measure. Ontario, Canada: Canadian Association of Occupational Therapists.

Lee, M. J., LaStayo, P. C., & vonKersburg, A. E. (2003). A supination splint worn distal to the elbow: A radiographic, electromyographic, and retrospective report.

Journal of Hand Therapy, 16, 190-198.

Lennon, S., & Ashburn, A. (2000). The Bobath concept in stroke rehabilitation: A focus group study of the experienced physiotherapist's perspective. *Disability and Rehabilitation, 22*, 665-674.

Lennon, S., Baxter, D., & Ashburn, A. (2001). Physiotherapy based on the Bobath concept in stroke rehabilitation: A survey within the UK. *Disability and Rehabilitation, 23*, 254-262.

Lin, K.-C., Hsieh, Y.-W., Wu, C.-Y., Chen, C.-L., Jang, Y., & Liu, J.-S. (2009). Minimal detectable change and clinically important difference of the Wolf motor function test in stroke patients. *Neurorehabilitation and Neural Repair, 23*, 429-434. Doi: 10.1177/1545968308331144

Luke, C., Dodd, K. J., & Brock, K. (2004). Outcomes of Bobath concept on upper limb recovery following stroke. *Clinical Rehabilitation, 18*, 888-898. Doi: 10.1191/0269215504cr793oa

Mackey, A. H., Miller, F., Walt, S. E., Waugh, M. C., & Stott, N. S. (2008). Use of three-dimensional kinematic analysis following upper limb botulinum toxin A for children with hemiplegia. *European Journal of Neurology, 15*(11), 1191-1198.

Mackey, A. H., Walt, S. E., & Stott, N. S. (2006). Deficits in upper-limb task performance in children with hemiplegic cerebral palsy as defined by 3-dimensional kinematics. *Archives Physical Medicine and Rehabilitation, 87*, 207-215. Doi:10.1016/j.apmr.2005.10.023

Mathiowetz, V. (2016). Task-oriented approach to stroke rehabilitation. In G. Gillen (Ed.), *Stroke rehabilitation: A function-based approach* (4th ed., pp. 59-78). St. Louis, MO: Elsevier.

Mathiowetz, V., & Bass-Haugen, J. (1994). Motor behavior research: Implications for therapeutic approaches to central nervous system dysfunction. *American Journal of Occupational Therapy, 48*(8), 733-745.

Mathiowetz, V., Bolding, D. J., & Trombly, C. A. (1983). Immediate effects of positioning devices on the normal and spastic hand measured by electromyography. *American Journal of Occupational Therapy, 37*(2), 247-254.

Mathiowetz, V., Kashman, N., Volland, G., Weber, K., Dowe, M., & Rogers, S. (1985). Grip and pinch strength: Normative data for adults. *Archives of Physical Medicine & Rehabilitation, 66*, 69-74.

McCall, M., McEwen, S., Colantonio, A., Streiner, D., & Dawson, D. R. (2011). Modified constraint-induced movement therapy for elderly clients with subacute stroke. *American Journal of Occupational Therapy, 65*, 409-418. Doi: 10.5014/ajot.2011.002063.

Mckee, P., & Rivard, A. (2004). Orthoses as enablers of occupation: Client-centered splinting for better outcomes. *Canadian Journal of Occupational Therapy, 71*(5), 306-314.

Mell, A. G., Childress, B. L., & Hughes, R. E. (2005). The effect of wearing a wrist splint on shoulder kinematics during object manipulation. *Archives Physical Medicine and Rehabilitation, 86*, 1661-1664.

Mell, A. G., Friedman, M. A., Hughes, R. E., & Carpenter, J. E. (2006). Shoulder muscle activity increases with wrist splint use during a simulated upper-extremity work task. *American Journal of Occupational Therapy, 60*, 320-326.

Mills, V. M. (1984). Electromyographic results of inhibitory splinting. *Physical Therapy, 64*(2), 190-193.

Morris, D. M., Uswatte, G., Crago, J. E., Cook, E. W. I., & Taub, E. (2001). The reliability of Wolf Motor Function Test for assessing upper extremity function after stroke. *Archives Physical Medicine and Rehabilitation, 82*, 750-755. Doi:10.1053/apmr.2001.23183

Murphy, T. H. & Corbett, D. (2009). Plasticity during stroke recovery: From synapse to behaviour. *Nature Reviews Neuroscience, 10 (12)*, 861-872. Doi: 10.1038/nrn2735

Nilsen, D. M., Gillen, G., Geller, D., Hreha, K., Osei, E., Saleem, G. T. (2015). Effectiveness of interventions to improve occupational performance of people

with motor impairments after stroke: An evidence based review. *American Journal of Occupational Therapy, 69*, 6091180030. http://dx.doi.org/10.5014/ajot.2015.011965

Nowak, D. A., Grefkes, C., Ameli, M., & Fink, G. R. (2009). Interhemispheric competition after stroke: Brain stimulation to enhance recovery of function of the affected hand. *Neurorehabilitation and Neural Repair, 23*, 641-656. Doi: 10.1177/1545968309336661

O'Dwyer, N. J., Ada, L., & Neilson, P. D. (1996). Spasticity and muscle contracture following stroke. *Brain, 119*, 1737-1749.

Ottenbacher, K. J., Branch, L. G., Ray, L., Gonzales, V. A., Peek, M. K., & Hinman, M. R. (2002). The reliability of upper- and lower-extremity strength testing in a community survey of older adults. *Archives Physical Medicine and Rehabilitation, 83*, 1423-1427. Doi:10.1053/apmr.2002.34619

Page, S. J., Levine, P., & Leonard, A. G. (2005). Modified constraint-induced therapy in acute stroke: A randomized controlled pilot study. *Neurorehabilitation and Neural Repair, 19*(1), 27-32. Doi:10.1177/1545968304272701

Page, S. J., Levine, P., Leonard, A., Szaflarski, J. P., & Kissela, B. M. (2008). Modified constraint-induced therapy in chronic stroke: Results of a single-blinded randomized controlled trial. *Physical Therapy, 88*, 333-340. Doi:10.2522/ptj.20060029

Page, S. J., Levine, P., Sisto, S., Bond, Q., & Johnston, M. L. (2002). Stroke patients' and therapists' opinions of constraint-induced movement therapy. *Clinical Rehabilitation, 16*, 55-60. Doi: 10.1191/0269215502cr473oa

Pereira, B. P., Thambyah, A., & Lee, T. (2012). Limited forearm motion compensated by thoracohumeral kinematics when performing tasks requiring pronation and supination. *Journal of Applied Biomechanics, 28*, 127-138.

Pinheiro, J. C. & Bates, D. M. (2000). Linear mixed-effects models: Basic concepts and examples. In Mixed-effects models in S and S-PLUS. Statistics and Computing. Springer, New York, NY.

Pitts, D. G. & O'Brien, S. P. (2008). Splinting the hand to enhance motor control and brain plasticity. *Topics in Stroke Rehabilitation, 15(5)*, 456-467. Doi:10.1310/tsr1505-456

Pizzi, A., Carlucci, G., Falsini, C., & Verdesca, S. (2005). Application of a volar static splint in post-stroke spasticity of the upper limb. *Archives Physical Medicine and Rehabilitation, 86*, 1855-1859.

Phillips, B. A., Lo, S. K., & Mastaglia, F. L. (2000). Muscle force measured using "break" testing with a hand-held myometer in normal subjects aged 20 to 69 years. *Archives Physical Medicine and Rehabilitation, 81*, 653-661. Doi:10.1053/mr.2000.4413

Preissner, K. (2010). Use of the occupational therapy task-oriented approach to optimize the motor performance of a client with cognitive limitations. *American Journal of Occupational Therapy, 64*(5), 727-734.

Radomski, M. V. (2011). More than good intentions: Advancing adherence to therapy recommendations. *American Journal of Occupational Therapy, 65*(4), 471-477.

Rao, A. K. (2016). Approaches to motor control dysfunction: An evidence-based review. In G. Gillen (Ed.), *Stroke rehabilitation: A function-based approach* (4th ed., pp. 348-359). St. Louis: Mosby.

R Core Team (2017). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, Retrieved from http://www.R-project.org/

Richards, L. G., Olson, B., Palmiter-Thomas, P. (1996). How forearm position affects grip

strength. *American Journal of Occupational Therapy, 50*, 133-138.

Reidy, T. G., Naber, E., Viguers, E., Allison, K., Brady, K., Carney, J., Salorio, C., & Pidcock,

F. (2012). Outcomes of a clinic-based pediatric constraint-induced movement therapy

program. *Physical & Occupational Therapy in Pediatrics, 32*, 355-367. Doi:

10.3109/01942638.2012.694991.

Safaee-Rad, R., Shedyk, E., Quanbury, A. O., & Cooper, J. E. (1990). Normal functional range of motion of upper limb joints during performance of three feeding activities. *Archives of Physical Medicine and Rehabilitation, 71*, 505-509.

Shindo, K., Fujiwara, T., Hara, J., Oba, H., Hotta, F., Tsuji, T., Hase, K., & Liu, M. (2011). Effectiveness of hybrid assistive neuromuscular dynamic stimulation therapy in patients with subacute stroke: A randomized controlled pilot trial*, Neurorehabilitation and Neural Repair, 25(9)*, 830-837. Doi: 10.1177/154968311408917.

Shumway-Cook, A., & Woollaacott, M. H. (2007). Motor control: Issues and theories. In A. Shumway-Cook, & M. H. Woollaacott (Eds.), *Motor control: Translating research into clinical practice* (3rd ed., pp. 3-20). Philadelphia: Lippincott Williams & Wilkins.

Sommerfeld, D. K., Eek, E. U. B., Svensson, A. K., & Holmqvist, L. W. (2004). Spasticity after stroke: Its occurrence and association with motor impairments and activity limitations. *Stroke, 35*, 134-139. Doi:10.1161/01.STR.0000105386.05173.5E

Ste-Marie, D. M., Vertes, K. A., Law, B., & Rymal, A. M. (2013). Learner-controlled self-observation is advantageous for motor skill acquisition. *Frontiers in Psychology, 3*, 1-10. Doi:10.3389/fpsyg.2012.00556

Steultjens, E. M. J., Dekker, J., Bouter, L. M., van de Nes, C. M., Cup, E. H. C., van de Ende, C. H. M., . . . Bernabei, R. (2003). Occupational therapy for stroke patients: A systematic review. *Stroke, 34*, 676-687. Doi:10.1161/01.STR.0000057576.77308.30

Stevenson, T. J. & Thalman, L. P. (2007). Effectiveness of a modified constraint-induced movement therapy regimen for upper limb ability after stroke: A retrospective case series. *Physiotherapy Canada, 59*, 99-110. Doi: 10.2310/6640.2007.00019.

Tangalos, E. G., Smith, G. E., Ivnik, R. J., Pertersen, R. C., Kokmen, E., Kurland, L. T., . . . Parisi, J. E. (1996). The mini-mental state examination in general medical practice: Clinical utility and acceptance. *Mayo Clinic Proceedings, 71*(9), 829-837. Doi:10.4065/71.9.829

Taub, E., Novack, T. A., Cook, E. W. I., Fleming, W. C., Nepomuceno, C. S., Connell, J. S., & Crago, J. E. (1993). Technique to improve chronic motor deficit after stroke. *Archives Physical Medicine and Rehabilitation, 74*, 347-354.

Taub, E., Uswatte, G., & Elbert, T. (2002). New treatment in neurorehabilitation founded on basic research. *Nature Reviews, 3*, 228-236. Doi:10.1038/nrn754

Taub, E., Uswatte, G., King, D. K., Morris, D., Crago, J. E., & Chatterjee, A. (2006). A placebo-controlled trial of constraint-induced movement therapy of upper extremity after stroke. *Stroke, 37*, 1045-1049. Doi:10.1161/01.STR.0000206463.66461.97

Taub, E., Uswatte, G., & Pidikiti, R. (1999). Constraint-induced movement therapy: A new family of techniques with broad application to physical rehabilitation-A clinical review. *Journal of Rehabilitation Research and Development, 38*(3), 237-251.

Tyson, S. F. & Kent, R. M. (2011). The effect of upper limb orthotics after stroke: A systematic review. *NeuroRehabilitation, 28*, 29-36. Doi: 10.3233/NRE-2011-0629

Urton, M. L., Kohia, M., Davis, J., & Neill, M. R. (2007). Systematic literature review of treatment interventions for upper extremity hemiparesis following stroke. *Occupational Therapy International, 14*, 11-27. Doi: 10.1002/oti.220

Uswatte, G., Taub, E., Morris, D., Light, K., & Thompson, P. A. (2006). The motor activity long-28: Assessing daily use of the hemiparetic arm after stroke. *Neurology, 67*, 1189-1194.

Van Andel, C. J., Wolterbeek, N., Doorenbosch, C. A. M., Veeger, D., & Harlaar, J. (2008). Complete 3D kinematics of upper extremity functional tasks. *Gait & Posture, 27*, 120-127. Doi:10.1016/j.gaitpost.2007.03.002

Van dee Lee, J. H., Beckerman, H., Knol, D. L., de Vet, H. C. W., & Bouter, L. M. (2004). Clinimetric properties of the Motor Activity Log for the assessment of arm use in hemiparetic patients. *Stroke, 35*, 1410-1414. Doi: 10.1161/01.STR.0000126900.24964.7e

Voss, D. E., Ionta, M. K., & Myers, B. J. (Ed.). (1985). Proprioceptive neuromuscular facilitation. Philadelphia: Harper & Row

Watanabe, T. (2004). The role of therapy in spasticity management. *American Journal of Physical Medicine and Rehabilitation, 83*, S45-S49. Doi: 10.1097/01.PHM.0000140130.58285.DA

Ward, N. S., Brown, M. M., Thompson, A. J., & Frackowiak, R. S. J. (2003). Neural correlates of outcome after stroke: A cross-sectional fMRI study. *Brain, 126*, 1430-1448. Doi: 10.1093/brain/awg145

Wittes, J., & Brittain, E. (1990). The role of internal pilot studies in increasing the efficiency of clinical trials. *Statistics in Medicine, 9*, 65-72.

Wolf, S. L., Caltin, P. A., Ellis, M., Archer, A. L., Morgan, B., & Piacentino, A. (2001). Assessing Wolf motor function test as outcome measure for research in patients after stroke. *Stroke, 32*(7), 1635-1639. Doi:10.1161/01.STR.32.7.1635

Wolf, S. L., Miller, J. P., Thompson, P. A., Taub, E., Uswatte, G., Morris, D., & Blanton, S. (2008). Retention of upper limb function in stroke survivors who have received constraint-induced movement therapy: The EXCITE randomized trial. *Lancet Neurology, 7*, 33-40. Doi: 10.1016/S1474-4422(07)70294-6

Wolf, S. L., Winstein, C. J., Miller, J. P., Taub, E., Uswatte, G., Morris, D., . . . Nichols-Larson, D. (2006). Effect of constraint-induced movement therapy on upper

extremity function 3 to 9 months after stroke: The EXCITE randomized clinical trial. *Journal of American Medical Assoication, 296*(17), 2095-2104.

Woodson, A. M. (2008). Stroke. In M. V. Radomski, & C. A. Trombly Latham (Eds.), *Occupational therapy for physical dysfunction* (6th ed., pp. 1001-1041)

Wu, C. Y., Chen, C. L., Tang, S. F., Lin, K. C., & Huang, Y. Y. (2007). Kinematic and clinical analyses of upper-extremity movements after constraint-induced movement therapy in patients with stroke: A randomized controlled trial. *Archives Physical Medicine and Rehabilitation, 88*, 964-970. Doi: 10.1016/j.apmr.2007.05.012

Yildizgoren, M. T., Yuzer, G. F. N., Ekiz, T., & Ozgirgin, N. (2014). Effects of neuromuscular

electrical stimulation on the wrist and finger flexor spasticity and hand functions in cerebral palsy. *Pediatric Neurology, 51*, 360-364. Doi: 10.1016/j.pediatrneurol.2014.05.009.

Appendix A

Test: Role Checklist

Participant's code: ___ Investigator:___ _____
Date: _____

Please check each category below according to your life roles:

Role	Role Identity			Value Designation		
	Past	Present	Future	Not at all valuable	Somewhat valuable	Very valuable
Student						
Worker						
Volunteer						
Care Giver						
Home Maintainer						
Friend						
Family member						
Religious participant						
Hobbyist/Amateur						
Participant in organizations						
Other:						
Other:						

Please add any further details/comments related to your roles in life:

Appendix B

Test: Interest Check List

Participant's code: _____
Investigator:_____
Date: _____

Please check each item below according to your interest

Activity	Level of Interest Within the past year			Level of Interest Within the past ten years			Do you currently participate in this activity?		Do you want to pursue this activity in the future?	
	Casual	Strong	No	Casual	Strong	No	Yes	No	Yes	NO
1 Gardening										
2 Sewing										
3 Poker										
4 Foreign languages										
5 Social clubs										
6 Radio										
7 Bridge										
8 Car repair										
9 Writing										
10 Dancing										
11 Needlework										
12 Golf										
13 Football										
14 Popular music										
15 Puzzles										
16 Holidays										
17 Solitaire										
18 Movies										

19 Lectures										
20 Swimming										
21 Bowling										
22 Visiting										
23 Mending										
24 Chess										
25 Barbecues										
26 Reading										
27 Traveling										
28 Martial arts										
29 Parties										
30 Dramatics										
31 Shuffleboard										
32 Ironing										
33 Social Studies										
34 Classical music										
35 Floor mopping										
36 Model building										
37 Baseball										
38 Checkers										
39 Singing										
40 Home repairs										
42 Volleyball										
43 Woodworking										
44 Billiards										
45 Driving										
46 Dusting										
47 Jewelry Making										
48 Tennis										

49 Cooking										
50 Basketball										
51 History										
52 Guitar										
53 Science										
54 Collecting										
55 Ping Pong										
56 Leatherwork										
57 Shopping										
58 Photography										
59 Painting										
60 Television										
61 Concerts										
62 Ceramics										
63 Camping										
64 Laundry										
65 Dating										
66 Mosaics										
67 Politics										
68 Scrabble										
69 Decorating										
70 Math										
71 Service Groups										
72 Piano										
73 Scouting										
74 Plays										
75 Clothes										
76 Knitting										
77 Hairstyling										
78 Religion										
79 Drums										
80 Conversation										

81 video games (Nintendo Wii)										
Other										
Other										

Appendix C

Test: Canadian Occupational Performance Measure (COPM)

Participant's ID code: _____ **Investigator: _____**

Date: _____

Tested UE: __R __L **Evaluation:** __Pre __Post1 __ Post2

For each issue or problem that you identified, fill out a performance score and a satisfaction score in the indicated boxes.

*Performance score: using the 1 to 10 Performance Scale below, **how well do you feel you perform this task?**
*Satisfaction score: using the 1 to 10 Satisfaction scale below, **how satisfied are you with you perform this task?**

Step 1: Identification of occupational performance issues: To identify occupational performance problems, concerns and issues, interview the client, asking about daily activities which they want to do, need to do or expected to do by encouraging them to think about a typical day. Then ask the client to identify which of these activities are difficult for them to do now to their satisfaction. Record these activity problems in steps 1A, 1B, or 1C.		**Step2: Rating Importance** Using the scoring card provided, ask the client to rate on a scale 1 to 10, the importance of each activity. Place the ratings in the corresponding boxes in steps 1A, 1B, or 1C.
Step 1A: *self care*		**Importance**
Personal care (e.g., dressing, bathing, feeding, hygiene)	_____ _____ _____	
Functional Mobility (e.g., transfers,	_____ _____	

indoor, outdoor)	_____	
Community management (e.g., transportation, shopping, finances)	_____ _____ _____	
Step 1B: Productivity		**Importance**
Paid/unpaid work (e.g., finding/keeping a job, volunteering)	_____ _____ _____	
Household Management (e.g., cleaning, laundry, cooking)	_____ _____ _____	
Play/school (e.g., play skills, homework)	_____ _____ _____	
Step 1B: Leisure		**Importance**
Quiet Recreation (e.g., hobbies, crafts, reading)	_____ _____ _____	
Active Recreation (e.g., sports, outing, travel)	_____ _____ _____	
Socialization (e.g., visiting, phone calls, parties, correspondence)	_____ _____ _____	

Step 3 & 4: Scoring-Initial Assessment and Reassessments

Confirm with the client the most 5 important problems and record them below. Using the scoring cards, ask the client to rate each problem on performance and satisfaction, then calculate the total scores. Total scores are calculated by adding

together the performance or satisfaction scores for all problems and dividing by the number of problems. At reassessment, the client scores each problem again for performance and satisfaction. Calculate the new scores and the change scores.						
Occupational performance problem	Assesment1 Date:		Assesment2 Date:		Assesment3 Date:	
	Performance	satisfaction	Performance	satisfaction	Performance	satisfaction
1.						
2.						
3.						
4.						
5.						
Scoring Total score = Total performance or satisfaction scores / # of problems	Prformance1 score: / =	Satisfaction1 score: / =	Prformance2 score: / =	Satisfaction2 score: / =	Prformance3 score: / =	Satisfaction3 score: / =

Change in performance1	Performance score 2 – Performance score 1 =
Change in satisfaction1	Satisfaction score 2 – satisfaction score 1 =
Change in performance2	Performance score 3 – Performance score 2 =
Change in satisfaction2	Satisfaction score 3 – satisfaction score 2 =


PERFORMANCE
1 2 3 4 5 6 7 8 9 10
not able to do it
able to do it extremely well
SATISFACTION
1 2 3 4 5 6 7 8 9 10
not satisfied at all
extremely satisfied

Appendix D-

Written Instructions for Orthosis care

Instructions for orthosis/splint use and care

The forearm rotation splint that you will wear on your weaker arm combines a wrist splint and a neoprene strap

- The wrist splint has a single pull lace closures. It allows you to easily put it on and adjust with one hand.
- The neoprene strap is Latex-free. This elastic strap will assist the forearm rotation movement of your weaker arm.

How to put on the splint:

- 1st Put on the wrist splint and fasten the Velcro strap of the splint. (Figure 1 and 2)
- 2nd Attach one end of the strap to the wrist splint at the **wrist level** of the *pinky side*. (Figure 3)
- 3rd Straighten your elbow with your palm facing the ceiling. (Figure 4)
- 4th Wrap the strap at an angle around the forearm, continuing up to the elbow. (Figure 5) **Do not wrap the strap too tight.** You don't want to restrict circulation.
- 5th Attach the end of the strap to itself. (Figure 6)

Figure 1.

Figure 2.

Figure 3.

Figure 4.

Figure 5.

Figure 6.

Stop using the splint if you have:

- Swelling of the weaker arm, or
- An allergic reaction producing redness, itching, burning or other skin problems, or
- Find the splint uncomfortable, or
- Have an open wound that would come in contact with the splint.

If you have any of these problems, please also contact the researcher, Chih-Huang (Jeffrey) Yu, immediately at (425)-985-5517.

Care and cleaning:

- Please hand wash the splint in ***warm water and mild soap*** as needed.
- **Do not wring.** Lay flat on towel. Dry at room temperature. Be sure the material is completely dry before reapplying.
- **Do not use ointments or oils** under the material.

Appendix E

Study flyer

UNIVERSITY OF MINNESOTA
Department of Rehabilitation Science

Seeking Persons Post-Stroke with Limited Use of their Affected Arm

Efficacy of a Forearm Rotation Orthosis
For Persons with a Hemiparetic Arm

You are invited to participate in a study to investigate the **efficacy of a forearm rotation orthosis/splint** combined with the Occupational Therapy (OT) Task-Oriented approach for upper extremity rehabilitation following stroke.

This orthosis is designed to assist forearm rotation by reducing the effects of gravity on your arm. We believe this assistance will enable you to perform daily activities, such as feeding and personal hygiene, more easily. All participants will receive the OT Task-Oriented Approach, which uses self-care, leisure, and work-related activities to enable you to use your affected arm more effectively. Half of participants will experience the orthotic intervention. If the efficacy of orthosis is confirmed, the orthosis will be provided for the other half of participants after the study. The study therapy sessions (3 hours per week for 6 weeks) will be provided at **no cost** to participants. **Participants will be paid $12 each session for transportation and parking costs**.

The training and evaluation will take place at the University of Minnesota (***Room 520,* Children's Rehabilitation building**) (426 Church St. SE, Minneapolis, MN 55455*)* for 7 weeks. The study will include another 6 weeks of no treatment or orthosis wear during which you don't need to come to the clinic.

To be eligible for this study you must be at least 3 months post stroke and must not be receiving rehabilitation for your affected arm at the time of the study. Your affected arm should have strength and range of motion limitations, which limits your ability to perform your daily life functional tasks.

If you have questions or would like to sign up for a screening session, please contact **Chih-Huang (Jeffrey) Yu** at the University of Minnesota,
Telephone: office: **(612) 626-2443**; Cell: **(425) 985-5517**
Email: **yuxxx648@umn.edu**

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Appendix F

Consent Form

CONSENT FORM

Study Title: Efficacy of a Forearm Rotation Orthosis for Persons with a Hemiparetic Arm

Study #: 1309M42881

Sponsor: N/A

Study Investigator: Chih-Huang (Jeffrey) Yu, Doctoral student, Rehabilitation Science program, Children's Rehabilitation Center,
426 Church St SE, Minneapolis, MN 55407

Telephone Number: (612) 626-2443

After Office Hours: (612) 626-2443

To contact the principal investigator (Chih-Huang Yu) directly, please call the PI's office phone number (612) 626-2443 or cell phone (425) 985-5517 between the hours of 9am and 5pm, or you may email him at yuxxx648@umn.edu.

Research Subject's Bill of Rights

People who volunteer to participate in an experiment (also called a research study or clinical trial) need to understand what is expected of them and why the research is being done. As you think about whether or not to volunteer, it is important that you know you have rights in place to help protect you. These rights, listed below, will be further explained as you read this consent form.

If you are asked to participate in a research study, you have the right to the following:

- Be told the purpose and details of the research study.
- Have the devices (implants, instruments, or tools) used in the research study described to you.
- Have the procedures of the research study and what is expected of you explained to you.
- Have the risks, dangers and discomforts of the research study described to you.
- Have the benefits and advantages of the research study described to you.
- Be told of other devices, or procedures (and their risks and benefits) that may be helpful to you.

- Be told of medical treatment available to you if you are injured because of the research study.
- Have a chance to ask questions about the research study.
- Quit the research study at any time without it affecting your future treatment.
- Have enough time to decide whether or not to take part in this research study and to make that decision without feeling forced or required to participate.
- Be given a copy of this signed and dated consent form.

You are being invited to participate in a research study to assess the effects of a forearm rotation splint on function in persons with a partially paralyzed arm due to stroke. The splint is designed to assist the forearm movement of your weaker arm during daily activities. You are being invited to participate because you are at least 18 years old, had a stroke at least three months ago that left you with at least partial paralysis in your arm, and are not currently receiving therapy for your arm.

We (the investigator and study staff) request that you read this form carefully and ask any questions you have before agreeing to be part of this study.

Study Purpose

After a stroke, people often have difficulties using one arm in activities. Forearm movements are necessary for many daily activities, such as eating and combing hair, but these movements are not usually emphasized in therapy to rehabilitate the arm. We believe that improving forearm movements may improve functional activities.

This study compares:

1. Participation in an occupational therapy called the Occupational Therapy (OT) Task oriented approach
2. Combination of use of a forearm splint and the OT Task oriented approach.

The Occupational Therapy Task oriented approach is not currently part of the standard of care for people with your condition.

Be aware that this form refers to the OT Task oriented approach and the activities involved with the forearm splint as "study procedures."

It is planned that about 40 people with an arm weakened by a stroke will be in this study.

Study Procedures

All assessments in this study will be provided at the study clinic.

- You will be assigned to one of two groups (Group A or Group B, outlined below) by chance through selecting a sealed envelope with your group assignment.

Based on current motor function condition of your weaker arm, you will first be classified as mild, moderate, or severe. You will then be randomly assigned to either Group A or Group B. Random assignment is like tossing a coin. You have an equal chance of being in either group. Neither you nor the investigator or study staff will be able to pick which group you are in. Regardless of group, in the first week of the study you will:

- Week 1: come to the clinic for a 2 hour assessment,
- Week 2-7: participate in one part of the study procedures for your group for 6-weeks,
- Week 8: return to the clinic for another 2 hour assessment,
- Week 9-14: participate in the second part of study procedures for your group for 6 weeks
- Week 15: return to the clinic for a final 2 hour assessment.

The plan looks like this:

		Week 1	**Week 2-7**	**Week 8**	**Week 9-14**	**Week 15**
Procedures	Group **A**	• 2-hour evaluation and splint construction • In the Study Clinic	• 1-1.5 hours- Splint fit and education in the Study Clinic • Use splint at home as much as possible • Wear the Nike+ FuelBand during daily routine • Phone contact with study investigator weekly or as needed	• 2-hour evaluation in the Study Clinic • You will not bring your splint to the evaluation or discuss it. • An evaluator who is unaware of your study group will check on your condition	• 2-3 visits for total of 3 hrs per week in the Study Clinic • Splint + OT task-oriented approach • Wear the Nike+ FuelBand during daily routine and in the Study Clinic	• 2-hour evaluation in the Study Clinic • You will not bring your splint to the evaluation or discuss it. • An evaluator who is unaware of your study group will check on your condition
	Group **B**	• 2-hour evaluation • In the Study Clinic	• Wear the Nike+ FuelBand during daily routine	• 2-hour evaluation in the Study Clinic	• 2-3 visits for total of 3 hrs per week in the Study Clinic	• 2-hour evaluation in the Study Clinic

			• Maintain usual daily routine • Home • Phone contact with study investigator weekly or as needed	• You will not discuss that you have only been following your usual routine. • An evaluator who is unaware of your study group will check on your condition.	• OT task-oriented approach study procedures • Wear the modified Nike+ FuelBand during daily routine and in the Study Clinic	• You will not discuss that you have only been following your usual routine. • An evaluator who is unaware of your study group will check on your condition.

a. Splint procedure.

i. **People in Group A** are the only ones to receive a splint as part of their study participation. The splint is composed of a commercial fabric wrist splint and a latex-free neoprene forearm strap that wraps around the forearm to assist forearm motion. **See the picture below. Although these splints are comfortable**, the study investigator will telephone you every week to ensure that you have having no problem with the splint during the study.

During the study, we ask that you **wear the splint as much as you can** during your home activities, and that you wear the Nike+ FuelBand (described below) to record your daily wear that the study staff will give you. We will collect this record at the end of the 6-week period.

b. OT task-oriented approach.

i. The goal of the OT task-oriented approach is to enhance your ability of using your affected arm in activities that are most important to you.

ii. The study procedure period will include three hours of study procedures per week (i.e., either three 1-hour sessions/week or two 1.5 hours sessions/week) for a period of six weeks

iii. We will use everyday functional activities matching your interests, video game systems (such as Wii or Interactive Rehabilitation Exercise), and the mobile arm supports (MAS) as needed to achieve the goals you set periodically.

a) The MAS is a device designed to assist your weaker arm in performing everyday self-care, productivity, and leisure related activities. Your arm should feel lighter while using the MAS so doing these tasks may become easier.

(2) If you are assigned to **Group B**, you will first undergo <u>six weeks of no treatment followed by another six weeks of OT task-oriented approach</u>.

c. Nike+ FuelBand:

i. The Nike+ FuelBand is a wristband designed to record how you use your weaker arm during a day, such as eating. It is water-resistant so you can wear it while showering. However, you should not wear it when swimming.

ii. If you are in Group A, you will wear the Nike+ FuelBand at your weaker wrist together with the splint during the study. You will wear the splint on top of the Nike+ FuelBand.

iii. If you are in Group B, you will wear the Nike+ FuelBand on your weaker wrist during the study.

iii. The study investigator will phone you every week to remind you to recharge the wristband by connecting it to a computer or any device with USB port.

iv. Please note that you will need to return the Nike+ FuelBand after you complete the study.

d. *Both groups will receive six weeks of the OT task-oriented approach intervention. The difference between the groups is whether you receive the splint or not.*

The same evaluations will occur at week 1, 8, and 15. An occupational therapist who is not involved in this study will perform the assessments. You will be assessed on:

1) Your voluntary reaching movements and manipulation of objects using the *Wolf Motor Function test*:
   a. This test will be videotaped for evaluation purposes. The video will show your entire body including your face. No one, except the study staff, will see these videos. You do not have to let the investigator or study staff take

video of you if you don't want to. You will indicate your choice about being videotaped at the end of this form.

2) Actual use of your involved arm using the *Motor Activity Log*.
    a. You will rate "how often" and "how well" you use your weaker arm in common functional activities.
3) Active and passive joint motion using standard clinical tool called a goniometer.
4) Muscle strength of the arm and grip using standard clinical tools called handheld and grip dynamometers.
5) Lastly, the investigator will ask you to identify, rank, and decide the top functional tasks in which you want to improve your performance and how well you perform in them using the *Canadian Occupational Performance Measure*.

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the investigator or study staff.
- Tell the investigator or study staff about any changes in your health or the way you feel.
- Tell the investigator or study staff if you want to stop being in the study at any time.

To maintain the integrity of the study, it is very important that you do not discuss the content of the study with the evaluator.

The investigator and study staff will ask to take photos of you at every visit to evaluate your progress. You can still be in the study even if you do not want the principal investigator or study staff to take the photos. You will indicate your choice at the end of this form.

Risks of Study Participation

The strap used for the splint in this study is made of Latex-free neoprene and the forearm component is a fabric commonly used for splints. However, there are always some persons who may be allergic to a specific material and may develop skin irritation. This is especially likely during hot days, when sweat may add to irritation.

Participants will need to remove the splint and contact the investigator if they demonstrate allergic irritation. Another possible risk of this study may be increased muscle soreness as the result of increased use of the arm. Lastly, some participants may feel movements restricted when wearing the splint during daily activities. In such cases, participants should remove the splint. Do not wear the splint while driving a vehicle or operating heavy machinery, or when near exposed flames or other similar situations.

Although the Nike+ FuelBand is a commercially available wristband, there are always some persons who may be allergic to a specific material and may develop skin irritation. This could occur during hot days, when sweat may add to irritation. The modified Nike+ FuelBand is made of the same material as the Nike+ FuelBand. Allergy to a specific material may happen and may develop skin irritation

Ask the investigator if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

Please tell the investigator or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study.

Video, photography and Confidentiality Risks

It is possible that people who see the video and photographs will recognize you.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the investigator or study staff if you would like to know more about how your information will be protected while you are in this study.

Could I have any other problems with my health if I am in this study?

It is possible that you could have problems and side effects of the study procedures that nobody knows about yet, which include your condition getting worse.

Benefits of Study Participation

Your participation in this study may or may not directly benefit you. Your stroke-affected arm might not get better or may even get worse while you are in this study. Information from this study might help researchers to better understand hemiparetic arm or come up with new tests or rehabilitation treatments to help others in the future.

Alternatives to Study Participation

If you do not want to participate in this study, you are not obligated to do so. You may still be treated for upper limb rehabilitation through a health care provider. However, some strategies used in this study might not be available to you elsewhere. You can receive a splint for your arm through your health care provider without participating in this study. You should discuss your alternatives to participating in this research with the investigator or study staff. In addition, you may discuss your options with your regular health care provider.

Study Costs

There are no costs to you for participating in the study.

Billing Error Information

If you believe you have received a bill in error during the research study, contact the investigator or study staff at the phone number listed on page one of this form.

Compensation

You will not be paid for your participation. We will pay you $ 12 dollars for parking and transportation for each research visit. However, you will need to pay for your own transportation.

If you are in Group A, you may keep the splint at no cost. If you are assigned to Group B, we will provide you a splint at no cost after you complete the study if you want one.

Research Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research-related injury, please let the principle investigator know about the situation immediately.

You do not give up any of your legal rights by signing this form.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Confidentiality

The records of this study will be kept strictly confidential. However, some funding and regulatory agencies such as the U.S. Food and Drug Administration (FDA) or other regulatory agencies in this and other countries may have the right to review the records of this study. These agencies include the University of Minnesota Institutional Review Board members and we will not disclose your name or any other personal information that could identify you as a participant. Every attempt will be made to disguise identifying features in assessment video recordings and pictures.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you.

At most, the Web site will include a summary of the results. You can search this Web site at any time.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

New Information

If there is any new information or knowledge that develops during the study or if there are any changes or modification to the research, the relevant information will be reviewed by the University of Minnesota and the study center and will be shared with you.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota and services you may be receiving from the study center or investigator. Even if you decide to participate, you are free to withdraw at any time without affecting those relationships or having any penalty or loss of benefits to which you are otherwise entitled.

The investigator or study staff can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The investigator or study staff believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you stop being in the study early, the investigator or study staff may ask you some questions about being in the study. The investigator or study staff may ask you to participate in some procedures or tests to help you leave the study safely and/or to collect more information for the study.

Contacts and Questions

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the investigator or study staff as soon as possible.

You can ask questions about the study at any time. You may ask any questions you have now, and if you have questions later, **you are encouraged to** contact the investigator or study staff at the phone number listed on page 1 of this form. You should call the investigator or study staff if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

If you have any questions or concerns regarding the study and would like to talk to someone other than the investigator or study staff, you are encouraged to contact the Research Subjects' Advocate Line..

The Research Subjects' Advocate Line is located at D-528 Delaware Street S.E., Minneapolis, Minnesota, 55455; telephone: (612) 625-1650.

You will be given a signed copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I voluntarily consent to participate in the study. By signing this form, I do not give up any of my legal rights.

The investigator and study staff would like to **videotape** you during the study to evaluate the effectiveness of the study procedures. You do not have to be videotaped to be in the rest of the study. Information about the videotaping is included earlier in this form. If, at any time, you change your mind about the videotaping, tell the investigator or study staff.

Initial below beside only one option:

_____ Yes, I agree to be videotaped for scientific/professional purposes for indefinite use.

_____ Yes, I agree to be videotaped for research purposes only (files will be erased within 1 year)

_____ No, I do not agree to be videotaped. I can still be in the rest of the study.

The investigator and study staff would like to **photograph** you during the study to evaluate the effectiveness of the study procedures. You do not have to be photographed to be in the rest of the study. Information about the photography is included earlier in this form. If, at any time, you change your mind about the photographs, tell the investigator or study staff.

Initial below beside only one option:

_____ Yes, I agree to be photographed for scientific/professional purposes for indefinite use.

_____ Yes, I agree to be photographed for research purposes only (files will be erased within 1 year)

_____ No, I do not agree to be photographed. I can still be in the rest of the study.

_____

Printed name of participant

_____ _____

Signature of participant Date

_____ _____

Printed name of person obtaining consent Role in study

_____ _____

Signature of person obtaining consent Date

Appendix G

Summary of Participants' Response regarding the OTTO intervention (N = 14).

Question:	Responses

What do you like about the OTTO intervention?	• Made me have the desire to use my right arm more
	• Treatment is wonderful
	  o Fingers were tight but now quite loose
	• All around, I enjoyed it
	• I keep thinking about what I can do at home
	• Gave me confidence about my performance
	• I feel like I'm making progress and that makes me happy
	• Every person we met here was super helpful and friendly
	• You gave me hope; gave me confidence
	• I will continue to use my arm
	• Oriented toward my goals
	• Tailored for treatment
	• Treatment was really good and fun
	  o iPad games;
	  o Real activities
	  ▪ Fun activities- those are my favorite
	  o Problem-solving
	  o Taught interesting things
	  o Use visual feedback
	  o Very encouraging
	  o Repetition- practice
	• Learn new techniques
	  o Learn to use the right muscles
	  o Home exercise
	• Receiving personal attention
	• Encouraging environment
	• Be accountable
	• Having a goal, task to achieve it
	• Fingers still don't work; wrist and elbow are weak, but shoulder is stronger
	Home exercise
	• Homework-relate to life; practical
	• Something different than I had before; not a waste of my time

What you do not like about the OTTO intervention?	• Too much home exercise- gets tired easily • Not really anything • None
Other issues indicated by participants related to the study	**Treatment period** • Treatment period too short • Length of treatment (study)- too long (15 weeks) **Schedule** • Scheduling- not the times I like • Restriction to time- don't have full access to treatment schedule (difficulty scheduling times that fit their schedule) **Other** • Study compensation is low • I don't like to travel for treatment • Evaluation- too hard